

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

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| IN RE: DEPUY ORTHOPAEDICS, INC. PINNACLE HIP IMPLANT PRODUCTS LIABILITY LITIGATION | (| MDL Docket No. |
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| | (| 3: 11-MD-2244-K |
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| This Document Relates to | (| |
| AOKI - 3: 13-CV-1071 | (| |
| CHRISTOPHER - 3: 14-CV-1994 | (| |
| GREER - 3: 12-CV-1672 | (| |
| KLUSMANN - 3: 11-CV-2800 | (| |
| PETERSON - 3: 11-CV-1941 | (| January 11, 2016 |

TRANSCRIPT OF TRIAL - VOLUME 2

BEFORE THE HONORABLE ED KINKEADE,

UNITED STATES DISTRICT JUDGE, and a jury

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Proceedings reported by mechanical stenography,
transcript produced by computer.

1 VOLUME 2 - TRIAL TRANSCRIPT - JANUARY 11, 2016

2 P R O C E E D I N G S

3 THE SECURITY OFFICER: All rise, come to order.

4 The United States District Court for the Northern
5 District of Texas is now in session, the Honorable District
6 Judge Ed Kinkeade presiding.

7 Let us pray.

8 God bless these United States and this Honorable Court.

9 Please be seated.

10 THE COURT: We're back on DePuy et al., MDL, cause
11 number 3:11-MD-2244-K.

12 I think we're ready to go.

13 Mr. Powell, was there something you wanted to address
14 before we got cranking?

15 MR. POWELL: Your Honor, I just wanted to say that
16 we did file a motion to ask Your Honor --

17 THE COURT: I was up at 2:30 and saw that. I was
18 just right there on it.

19 MR. POWELL: Very good. We would move the court to
20 preclude discussions of punitive damages in the opening
21 statements.

22 THE COURT: You want me to bifurcate?

23 MR. POWELL: Yes.

24 THE COURT: And I've already ruled against that. I
25 think what your motion says is that until the Fifth Circuit

1 rules I should consider all of that section -- I forgot the
2 number of it -- as substantive.

3 MR. POWELL: Yes.

4 THE COURT: Which would require me to bifurcate.

5 MR. POWELL: Yes, sir

6 THE COURT: I just want to make sure the record
7 says, because that's your new argument. I'm not saying it's
8 not a good argument. I think it's a good argument, but I'm
9 still going to overrule that.

10 Okay. Thank you.

11 Deny that. Excuse me.

12 Okay. How long did I give y'all for opening statements?

13 Who's going to make opening statements?

14 Mr. Sarver?

15 By yourself?

16 MR. SARVER: It's the best I can do.

17 THE COURT: By yourself, Mr. Lanier?

18 MR. LANIER: No, Your Honor. Mr. Cannon will help
19 me.

20 THE COURT: I don't know if I messed up on the
21 timing. I tend to cut y'all short when I think lawyers are
22 getting boring. Sorry. I won't do that today. I won't do
23 that today. I won't cut y'all off today.

24 MR. LANIER: I'll try not to be boring, Your Honor.

25 (Laughter)

1 THE COURT: I'm kidding you. I don't intend to do
2 that. Occasionally I mess up on the time.

3 Anything else?

4 MR. LANIER: With the court's permission, the way
5 we'll probably divide it up is I'll go for about 55 minutes or
6 so. Mr. Cannon will go for thirty minutes or so and leave me
7 about five minutes to finish up.

8 THE COURT: That's pretty close.

9 MR. LANIER: Thank you, Your Honor.

10 THE COURT: Mr. Sarver, do you need me to give you
11 any kind of warning or anything?

12 MR. SARVER: If you could tell me when I'm about
13 five minutes.

14 THE COURT: Five minutes. Okay. You bet.

15 And you're going to stay by the podium or within
16 arms-length touching the podium.

17 MR. LANIER: Yes, Your Honor.

18 THE COURT: I'm looking at you, Mr. Lanier, when I
19 say that because you're the one that extends to Stretch
20 Armstrong it. Do you remember that toy?

21 MR. LANIER: I will not be Stretch Armstrong today.

22 THE COURT: It will be hard to hear you, this one on
23 the podium right here if you get too far.

24 If I hum-hum, that's what that means, is you're messing
25 up.

1 MR. SARVER: Your Honor, the only time we might
2 stray a bit --

3 THE COURT: Is when you're showing something on the
4 podium.

5 MR. SARVER: Show and tell a little bit.

6 THE COURT: You got a loud voice. Make sure when
7 you have your back to Ms. Wilson -- I don't care how loud your
8 voice is in here, it's just hard to hear you. And I'll be
9 watching for that.

10 MR. SARVER: Yes, sir.

11 Pam, I'll do my best.

12 THE COURT: Y'all aren't going to go over here and
13 try to get in the jury box. No?

14 Okay. All right. I'm trying to think whatever else
15 y'all -- since the last time.

16 How long has it been since we tried that last case
17 together? Two years?

18 MR. LANIER: 14 months, Your Honor.

19 THE COURT: 14 months, 12 days, six hours, two
20 minutes, something like that.

21 MR. LANIER: Yes, Your Honor.

22 MR. SARVER: Seems like just yesterday.

23 THE COURT: Okay. All right. Well, I'm going to
24 read my instructions. I don't know if I showed y'all those or
25 not, but it's nothing I haven't already said. I did add

1 something with the individual cases not very different from
2 what I said to Ms. Tjarks during the voir dire.

3 Do I have any of my Baylor students here today?

4 No. Kids from other schools?

5 Somebody from SMU?

6 Just a bunch of lawyers.

7 Oh, wow. Okay. All right. I think we're ready.

8 THE COURT: Good morning, ladies and gentleman.

9 Stand up and I'll give you -- Actually, Mr. Jacobson is
10 going to give you your last oath that you will take in this
11 trial.

12 If you will raise your right hand.

13 Mr. Jacobson.

14 (Jury sworn.)

15 THE COURT: Okay. Y'all be seated.

16 One of my staff brought y'all some donuts. I hope y'all
17 didn't eat all of those. This is a chance for y'all to really
18 gain a lot of weight while you're down here. We will try to
19 do that occasionally.

20 I notice you remembered to bring something warm to wear.
21 That's good too. I'll try to regulate that. As the weather
22 in Texas, of course, is hot and cold, sometimes that's hard to
23 regulate. But I promise I will do my best.

24 The second thing is don't eat a big lunch today and don't
25 until you kind of get used to this. Y'all are not used to

1 sitting listening to lawyers talk, talk, talk, talk, talk. I
2 don't know how many talks that was, but Ms. Wilson could tell
3 me. It's just different. It's tiring. It really is. And
4 you need to be alert. So if you eat chicken fried steak and a
5 big piece of cake -- kind of sounds good -- at lunch, you
6 know, just think about that. We're going to bring you lunch
7 in today. I think y'all ordered that Friday. We'll do that
8 every day. That will save us about 30 minutes every day of
9 your time being able to get -- to get right back at that.

10 Let me read you some additional instructions that I think
11 will help you with your job.

12 You've now been sworn in as the jury to try the case, and
13 as the jury you will decide the disputed questions of fact.
14 As the judge, I will decide all questions of law and
15 procedure.

16 From time to time during the trial and at the end of the
17 trial, I will instruct you on the rules of law that you must
18 follow in making your decision. Soon the lawyers for the
19 parties will make what is called an opening statement. In
20 fact, right after I get through reading this to you.

21 Opening statements are intended to assist you in
22 understanding the evidence. What the lawyers say is not
23 evidence. After the opening statements the plaintiff will
24 call witnesses and present evidence. Then the defendant will
25 have an opportunity to call witnesses and present evidence.

1 And they have indicated to me they are going to do that.

2 After each parties' main case is completed, the opposing
3 party will be permitted to present rebuttal evidence. After
4 all the evidence is completed the lawyers will again address
5 you to make final arguments. That will be several weeks from
6 now. Then I will instruct you on the applicable law. You
7 will then retire to deliberate on a verdict.

8 Keep an open mind during the trial. Do not decide any
9 fact until you've heard all the evidence, the closing
10 arguments, and my instructions.

11 Pay close attention to the testimony and evidence. If
12 you would like to take notes during the trial, you may do so.
13 If you do take notes, be careful not to get so involved in
14 note taking that you become distracted and miss part of the
15 testimony. Your notes are to be used only as aids to your
16 memory, and if your memory should later be different from your
17 notes, you should rely on your memory and not on your notes.
18 If you do not take notes, rely on your own independent memory
19 of the testimony. Do not be influenced -- unduly influenced,
20 excuse me, by the notes of another juror. A juror's notes are
21 not entitled to any greater weight than the recollection of
22 each juror concerning the testimony.

23 Even though the court reporter is making stenographic
24 notes of everything that's said, a typewritten copy of the
25 testimony will not be available for you -- for your use during

1 deliberations. However, if you have a specific disagreement
2 as to a particular witness' testimony on a specific subject,
3 we can attempt to obtain that information for you. On the
4 other hand, any exhibits admitted during the trial will be
5 available to you during your deliberations.

6 Until this trial is over, do not discuss this case with
7 anyone and do not permit anyone to discuss this case in your
8 presence. Do not discuss the case even with other jurors,
9 even among yourselves, until all the jurors are in the room
10 actually deliberating at the end of the case.

11 I know that many of you use cell phones, iPhones,
12 BlackBerries. There's still BlackBerries out there. The
13 Internet, and other tools of technology.

14 You must not talk to anyone about this case or use your
15 tools -- iPads, iPhones -- to communicate electronically with
16 anyone about the case. This includes your family and friends.
17 You may not communicate with anyone about the case on your
18 cell phone, through email, BlackBerry, iPhone, text messaging,
19 on Twitter, through any blog or -- excuse me -- Internet chat
20 room or by way of any social networking web sites, including
21 Facebook, My Space, LinkedIn YouTube and some new ones I don't
22 even know.

23 If anyone should attempt to discuss this case or approach
24 you concerning the case, you should inform the court
25 immediately.

1 You can tell Mr. Everett, who is the court service
2 officer, and he'll immediately get with me.

3 It is important not only that you be fair and impartial
4 but that you appear to be fair and impartial.

5 Do not make any independent investigation of any fact or
6 matter in this case. You are to be guided solely by what you
7 see and hear in this trial.

8 In other words, you don't do any research, look on the
9 Internet, do anything like that on your own.

10 Do not try to learn anything about the case from any
11 other source.

12 During the trial, it may be necessary for me to confer
13 with the lawyers out of your hearing or to conduct a part of
14 the trial out of your presence. I promise you that will
15 happen. I will handle these matters as briefly and as
16 conveniently for you as I can, but you should remember that
17 they're just a necessary part of the trial.

18 The evidence in this case will consist of the following:
19 The sworn testimony from witnesses who will get in this chair
20 right here next to me, and that's of all the witnesses no
21 matter who called a witness; all exhibits received in evidence
22 regardless of who may have produced the exhibits; all facts
23 that may have been stipulated or judicially noticed that you
24 must take as true for purposes of this case.

25 A stipulation is an agreement between both sides that

1 certain facts are true. When the lawyers on both sides
2 stipulate or agree to the existence of a fact, you must,
3 unless otherwise instructed, accept the stipulation as
4 evidence and regard that fact as proven.

5 I may take judicial notice of certain facts or events.
6 When I declare that I will take judicial notice of some fact
7 or event, you must accept that fact as true.

8 If I sustain an objection, that will happen, too, I
9 promise, to any evidence, or if I order the evidence stricken,
10 that evidence must be entirely ignored.

11 During the trial, the lawyers may make objections to
12 questions asked or answers given. That simply means the
13 lawyer is requesting that I make a decision on a particular
14 rule of law. Do not draw any conclusion from those objections
15 or from my ruling on the objections. These relate only to the
16 legal questions that I must determine and should not influence
17 your thinking.

18 If I sustain an objection to a question -- and that will
19 happen -- the witness cannot answer. Do not attempt to guess
20 what answer might have been given had I allowed the question
21 to be answered.

22 If I overrule an objection, treat the answer like any
23 other.

24 Additionally, some evidence may be admitted for a limited
25 purpose only. When I instruct you that an item of evidence

1 has been admitted for a limited purpose only, you must
2 consider it only for that limited purpose and for no other
3 purpose. You are to consider only the evidence in the case.
4 From the facts that you believe have been proven, you may draw
5 such reasonable inferences or conclusions as you feel are
6 justified in light of your own experiences.

7 As we discussed briefly during jury selection the case on
8 trial involves eight separate plaintiffs from five separate
9 cases. It was my decision, not the parties, to consolidate
10 multiple cases into a single trial for the purposes of
11 judicial efficiency. Although the five cases concern claims
12 involving the Pinnacle metal-on-metal hip, the law requires
13 you to consider each claim by each plaintiff separately.

14 Five of the plaintiffs were implanted with a Pinnacle
15 metal-on-metal device, and the remaining three plaintiffs have
16 alleged a claim for loss of consortium because they are the
17 wives or husbands of the affected patients. Although you are
18 a single jury, I am instructing you to consider each of the
19 five cases and eight plaintiffs separately. You must consider
20 the evidence presented during this trial separately for
21 liability and separately for damages.

22 At the conclusion of the trial, I will provide you
23 additional instructions about the specific claims and defenses
24 of the parties and you will be asked to answer separate
25 questions for each plaintiff.

1 Listen carefully to the evidence presented as to each
2 plaintiff so you will be able to answer those questions.

3 It's now time for opening statements.

4 Mr. Lanier.

5 MR. LANIER: May it please the court.

6 THE COURT: Yes.

7 MR. LANIER: Your Honor, thank you.

8 Ladies and gentlemen of the jury, good morning. I
9 appreciate y'all being here very, very much. I know this is
10 not your first choice for what you're doing, but it makes the
11 world of difference, not only to our clients, but I think it
12 makes a world of difference to our community as well. I'll
13 explain why as we go through this.

14 I was trying to figure out how to present the opening
15 statement as best as I could, and I decided that -- that a lot
16 of us don't read that much anymore, in terms of books, most of
17 us do our reading online and things like that, but to me this
18 just fit a book.

19 And so if you will excuse me I've made up a book and it's
20 in the PowerPoint that you see behind me. The book is "The
21 Account of a Medical Experiment Gone Wrong."

22 And I believe that's what this case is about.

23 Now, His Honor has given each side an hour and a half to
24 give an opening statement, which is an overview of what the
25 case is like. I'm going to speak for about 55 minutes, Your

1 Honor, if the court would allow it. And then when I'm through
2 Mr. Cannon has got about 30 minutes or so. And I may get five
3 minutes at the end, or whatever time Mr. Cannon leaves me, and
4 I'll get a chance to do that. And that's what you've got.

5 When we're done, whatever time His Honor determines, the
6 other side will then give his opening statement. They've got
7 that hour and a half as well.

8 Now, the account of a medical experiment gone bad here's
9 the table of contents, the forecast. I'm giving to give you
10 an instruction. I'm going to talk to you about all three
11 chapters: The Seduction, The Truth, and The Consequences.
12 And then we'll talk about the Conclusion or the Epilogue after
13 that.

14 So let's start with the introduction:

15 This case is about five people who trusted a product.
16 They trusted their doctor. And they got a terrible result.

17 The five people are in this courtroom. Earnest will
18 introduce them to you in more detail. I've got pictures of
19 them up here right now. Earnest will tell you all about them,
20 because in a very real sense they're the central part of this
21 case. They're what this case is about.

22 But in the process of this, all of these people bought a
23 DePuy J & J Pinnacle metal-on-metal hip implant.

24 Now, DePuy and Johnson & Johnson are the companies that
25 make it. Pinnacle is the name of the brand. It's like buying

1 a Ford as opposed to a Chevy. So Pinnacle is the name of the
2 brand.

3 And then metal-on-metal is the kind of hip implant.

4 Your Honor, may I have the freedom to grab some things?

5 THE COURT: Yes.

6 MR. LANIER: Thank you.

7 THE COURT: Yes.

8 MR. LANIER: So I've -- I've got -- as I stay within
9 an arms-length of the podium, I've got a couple of real ones
10 here that you've got a chance to see.

11 This is the stem. This is what goes into the thigh bone.
12 They cut off the top of the thigh bone and dig out and put
13 this stem in.

14 And then they've got to put a ball -- a ball goes on the
15 stem. And then on the hip side -- that's the thigh side. On
16 the hip side they ream out a hole, looks like a cheese grater.
17 And I think Mr. Sarver has the tools, he can show them to you
18 because they make the tools to do this as well.

19 But they will put in a cup into your bone, into your hip
20 bone, and inside that cup they're going to put a liner. They
21 can put a metal liner or they can put a plastic, or poly,
22 liner. And then that ball will fit into the liner and move
23 around.

24 So they have choices. They can use poly, or "plastic" is
25 another word for it, or they can use metal. And they put it in

1 there and it moves around.

2 So that what's we're talking about when I say each of
3 them got a metal-on-metal. For each of them the ball was
4 metal and it went into a metal liner, and so that's where they
5 got their materials from.

6 Now, DePuy -- I listened to the voir dire that was done
7 by Mr. Powell, a great Dallas lawyer who has been doing this
8 for a long time. He did a marvelous job. He said you
9 probably haven't heard of DePuy, they're a small -- or they're
10 a company up in Warsaw, Indiana, well -- started in 1895 by
11 Mr. DePuy.

12 That's not really who we're talking about. This is not
13 some family-run research-driven company.

14 What DePuy really is, is a multibillion dollar
15 multinational company that spends more time and more money
16 selling their products than they do doing their homework, than
17 they do research and development.

18 They've got plants, this is one I believe over in
19 England, Leeds England. They're all over the world.

20 When Johnson & Johnson bought the company in the '90s
21 Johnson & Johnson paid 3.5 billion dollars for the company.

22 So this is not a little -- little place up in Warsaw, I
23 Indiana, you know, mom and pop. It's not at all. That's not
24 what it is.

25 And as for Johnson & Johnson yes, they do make baby

1 powder and yes, they do make Listerine, but this is not your
2 baby's Johnson & Johnson we're going to be talking about here.
3 And you're going to see it from the inside and you're going to
4 see some things that frankly will make you sick at your
5 stomach. But we will show it to you and you will learn the
6 inside of this.

7 If I've placed you guys correctly, you are the perfect
8 jury for this case. And while I don't -- none of us know each
9 other well, if I remember correctly you've got among you one
10 of the top debaters in the country my senior year of high
11 school. You've got among you people who teach, either teach
12 children or teach adults. You've got among you social
13 psychologists. You've got among you people who interact with
14 folks and have good common sense. That's the kind of jury
15 that you've got here. And y'all get to figure out what
16 happened. You get to figure out why it happened. And you get
17 to figure out how to fix it. It's an awesome job that will
18 make a difference in this country as you see the way medical
19 device practice has been in the past and a chance to speak on
20 that and whether or not it's acceptable.

21 So that's where we are. Here's chapter 1, The Seduction.

22 By the way, I don't make that up. I get that word from a
23 PowerPoint that was presented -- Juan, can we go to the ELMO,
24 please -- a PowerPoint that was presented by a doctor of
25 DePuy's choosing. This is one of DePuy's doctors they use to

1 help sell the Pinnacle product. He made this presentation
2 just a few years ago, Dr. Fehring. And you will hear his
3 deposition. You will hear who he is. You will hear him talk
4 about how horrible this device has been, the metal-on-metal.
5 THA stands for Total Hip Arthroplasty. Just means hip
6 implant. Okay?

7 So this is not supposed to look like that when you cut
8 someone's area open.

9 And he's the one who made the presentation: "How did we
10 get here? Hip surgeons were seduced into using
11 metal-on-metal. They were seduced by manufacturers, DePuy,
12 Johnson & Johnson. They were seduced by patients, because
13 patients would watch the advertisements and say, hey, I just
14 saw that DePuy ad with Coach Krzyzewski, I want that, I want
15 that hip. And then they seduced themselves because these
16 doctors went around and told everybody to use the product. He
17 even defines what "seduction" means: "To lead someone astray
18 into a behavior of choice they may not otherwise make."

19 So when I talk about this being a seduction, I'm use
20 using a term that is -- is from DePuy's doctors.

21 Here's how we got there.

22 In the 1960's and '70s metal-on-metal implants were
23 failing at a massive rate. I'm not saying there weren't some
24 successful ones. They did some autopsies on some people. And
25 for some people the metal-on-metal hip implant would work for

1 30 years. But statistically, more times than not, it was a
2 massive failure.

3 So one of the forefathers of modern hip design is a
4 fellow from England now deceased named Sir John Charnley. And
5 he invented the idea of metal-on-poly.

6 Now, if anybody knows anything about cars they know when
7 your oil light comes on you better check your oil because no
8 one is going to run a car engine with metal-on-metal without
9 there being oil present. It's a recipe for disaster.
10 Heavens, our chairs squeak every time we roll back and forth
11 because it's metal-on-metal and it needs some oil. And -- and
12 that's just the way it is.

13 So Sir John Charnley said I'm, instead of doing
14 metal-on-metal, I'm going to do metal-on-poly.

15 Now, both of these will have some wear, but the body will
16 react differently to the metal wear than it will the wear from
17 the plastic, the poly.

18 So Sir John Charnley invented a metal-on-poly hip that
19 took the world by storm. It was not perfect but it was very,
20 very good. And that became the standard all over the world.

21 Now, because it was not perfect, even though it was the
22 best by far, scientists were always trying to figure out a way
23 to make it better. If you're good for 95 percent of the
24 people let's try to be good for 96 percent.

25 And so scientists were working on the poly to make

1 changes to it. They made good changes. They also made some
2 bad changes that didn't work. But they were always tinkering
3 with it to make it better.

4 DePuy and some others decided that they had a better
5 idea, they'd go back to the metal-on-metal, the failed past.
6 DePuy said -- and Johnson & Johnson, DePuy said, you know, if
7 we make a metal-on-metal we're going to make a lot more money,
8 because what we can do is we can tell everybody that this is
9 the greatest, best thing, and you don't need to -- to wait
10 until later in life to get a hip implant, we'll put them in
11 you when you're young, because it's going to last forever.

12 And so that's what they did.

13 Now, DePuy knew they had to act fast. J & J, DePuy knew
14 that the sooner they got to market the bigger their market
15 share. So they wanted to say we're going to get into the
16 market with this brand-new metal-on-metal. But if we're going
17 to do it we've got to get their really fast 'cause other
18 people are trying to do that too. Other people are doing
19 their experiments. Other people are -- are checking it out to
20 see if it's going to work or to see if they can design it
21 better or do something like that.

22 So DePuy was in a hurry.

23 And because they were in a hurry, they knew, DePuy knew,
24 that they had not solved the problem of metal-on-metal without
25 oil or some lubrication in the middle.

1 But even though they hadn't solved the problem, they went
2 to market anyway. They did not wait to test it.

3 In fact, what you're going to find out is DePuy,
4 Johnson & Johnson, told the doctors that they'd solved the
5 metal-on-metal problem.

6 You will see some marvelous pictures like this one.

7 This is a picture that DePuy was famous for using where
8 they said we have devised an implant where it's engineered so
9 well that there is full fluid film lubrication. The body puts
10 a full layer of lubrication between the liner and the head, so
11 that the metals do not touch each other, and you don't have to
12 worry about the metal debris getting in your body, which
13 everybody knew was toxic, would kill cells and kill muscle
14 tissue and do a lot of damage.

15 So DePuy told the doctors, we've solved this
16 metal-on-metal problem. And they went to market. They went
17 to market around the year 2000/2001, with metal-on-metal.

18 And then to sell this seduction DePuy found some doctors
19 that were willing to take money to go around the country and
20 tell everybody this is fantastic.

21 Some of these doctors they said were -- well, they called
22 them inventors or something of the metal-on-metal, which I
23 guess means the doctor has skin in the game. But what they
24 would do -- I've looked at the patents, I don't see that these
25 doctors were all inventors that were getting paid for this,

1 but they picked their key doctors and they would pay these key
2 doctors to go around the country touting the benefits of this
3 metal-on-metal and then they'd give the doctors a cut of every
4 one that was sold.

5 So these doctors are raking in millions upon millions of
6 dollars, a whole lot more off of selling these metal-on-metal
7 implants than they ever made practicing medicine. But they
8 would go around the country and do it.

9 And that was -- you know, some products sell themselves;
10 not this one. This one took a bunch of doctors and a bunch of
11 people to sell it.

12 J & J then would tell the world, not just the medical
13 community, but you and me if we're reading Woman's Day
14 magazine or if we're reading -- they put it in Golf magazine.
15 They put it in every magazine that they thought that older
16 people might read. And they would tell everybody -- they
17 printed up thousands, tens of thousands, hundreds of thousands
18 of brochures to put in all the doctor's offices and everywhere
19 else, telling everyone that their metal-on-metal was wildly
20 successful.

21 You're going to hear -- the one study they cited the
22 most, more than any other, in all of their literature and
23 everything else, was one that said this was 99.9 percent
24 successful at five years out from surgery.

25 And I can't wait until you get to hear about that study,

1 because it's the most bogus study you've ever seen in your
2 life. It's just flat wrong. I mean, it's just -- it's
3 appallingly wrong. And I'm going to show it to you. And
4 you'll be the first to see it. It's evidence that's been
5 marked confidential by DePuy and no one has ever been able to
6 see it before until this courtroom. And for the first time
7 you're going to see the evidence that the study they told all
8 the orthopedists was profoundly beneficial to the product was
9 in fact -- it's just -- it's -- it's a lie. It's just not
10 true. And I'll show you that. We'll walk through it.

11 Now, here's the truth, chapter 2.

12 DePuy knew metal-on-metal wasn't going to work. They
13 knew it from the outset. They had -- their chief fellow on
14 this was a man named Graham Isaac. And Graham Isaac wrote
15 this paper in 1995.

16 The paper is entitled "End Game." And this was internal
17 within DePuy. They didn't send this out to anybody. End
18 game, the failure of total hip replacement by the development
19 of manager of DePuy's hips.

20 And here's what he said, he talks about what causes
21 failure. And he talked about the failure with metal-on-poly,
22 which was the major one out there. And we can show you
23 examples of poly liners that fail. It was not perfect but it
24 was really good.

25 Here's what he says. "What are the alternatives?"

1 "There are two bearing surface combinations." The
2 bearings are the part that meet. It's the ball and it's the
3 liner. "There are two bearing surface combinations in use
4 which do not have a," plastic or, "Polyethylene component."

5 There's ceramic-on-metal and there's metal-on-metal, both
6 of which have identical surfaces, metal, metal, articulating
7 or moving against each other, "which would normally be
8 considered -- "normally considered to be bad engineering
9 practice."

10 Just common sense tells you, you don't do that.

11 He goes on to say it is clear -- and we just lose some
12 power.

13 Your Honor . . .

14 THE COURT: We got it figured out?

15 Okay. We'll take a little short break. You need to
16 understand, we're not as -- it's not the lawyer's fault it's
17 usually our court's fault. Things will go wrong with our
18 technology because we're government.

19 (Laughter.)

20 THE COURT: But we are. I have great folks that
21 work with it, but we have people that bid at the lowest price
22 and that's what we get.

23 So let's work on it just a minute. And we'll let y'all
24 know.

25 Don't talk about the case. It's our first break.

1 Thank y' all very much.

2 THE SECURITY OFFICER: All rise.

3 (Recess taken at 9:40.)

4 (Proceedings resumed at 9:43.)

5 THE SECURITY OFFICER: All rise for the jury.

6 (Jury enters the courtroom.)

7 THE COURT: Okay. Y' all be seated.

8 I think we've temporarily fixed it, best we can for now.

9 MR. LANIER: Your Honor, if you could go back to
10 PowerPoint real quick.

11 May I continue?

12 THE COURT: Yes, sir.

13 MR. LANIER: Thank you, Your Honor.

14 Nice thing about a book, you can put it down and pick it
15 back up. So we'll pick back up with our book.

16 J & J, they knew metal-on-metal wasn't going to work.
17 They absolutely knew it. They started selling it 2001/2001.

18 Your Honor, if we'll go back to the ELMO, please, or
19 Jesse.

20 Thank you guys.

21 Here's the memo they did internally, Graham Isaac did,
22 "End Game: The failure of total hip replacement by the
23 manager." He talked about the alternatives of metal-on-metal
24 and ceramic-on-ceramic and said that it is normally considered
25 bad engineering practice. That's just where he starts out

1 talking about where they're going to end up in the end game.

2 He goes on to say when he analyzes metal-on-metal, "It is
3 clear from the literature the survivorship of cobalt chromium,
4 metal-on-metal prostheses" -- that means implants -- "in the
5 past has been far from satisfactory."

6 Here's the problem. You put one of these in your hip and
7 it goes wrong, you got to get it out. And you think putting
8 it in is a problem, wait until you hear about getting it out.
9 And you get it out, and you just hope and pray you do it
10 before it destroys a bunch of muscle.

11 So here's what he said. He was very clear. He spoke
12 about it and he said, "While cobalt chromium components may be
13 manufactured optimally" -- We can make them the best science
14 will let us. We can say we've got brand-new ways to make
15 things they didn't have ten years ago. It's the best in the
16 world, he says "There is no guarantee this quality can be
17 maintained, and if the surfaces break down the debris produced
18 has been shown to be more harmful than plastic."

19 And it is.

20 Mr. Sarver is going to get up here -- Mr. Sarver is this
21 lawyer back here in the corner. He's going to get up here and
22 give the opening statement. He's going to show you all the
23 problems with plastic. And every time he shows you a problem
24 with plastic, you remember what the company knows -- because
25 I'll prove it during the trial -- and that is the debris

1 produced from metal is even worse than what you're seeing with
2 plastic. So as bad as plastic is, it's worse than with metal.
3 That's where this fellow goes.

4 He says so while the problem with of wear is present, the
5 results of -- This is poly. He's talking here about plastic.
6 He says the appropriate question, what's the problem, look at
7 the long term results of metal-on-plastic. And he talks about
8 those. And he says "So whilst" -- You can tell he's from
9 England "Whilst the problem of wear is present, the results of
10 plastic, poly, are still excellent when compared with the
11 results from metal-on-metal given above."

12 And his ultimate conclusion: "The alternatives to
13 metal-on-poly have either mixed results" -- which is
14 ceramic-on-ceramic -- "or are building upon past failures --
15 metal-on-metal -- "with partial solutions in the hope of
16 future success."

17 That's what the company knew.

18 And in spite of that, the company decides that they're
19 going to go forward and start selling these.

20 I asked Mr. Isaac in his deposition -- And I don't think
21 he'll come over from England for this case. But I asked him
22 in his deposition to help us with the timeline. And here's
23 the timeline. He wrote this in 1995 about metal-on-metal
24 failures and the problems with the debris and the little metal
25 ions.

1 In 2001, they started selling the Pinnacle metal-on-metal
2 anyway. And at that time he had to admit under oath nobody
3 knew what was a safe level of debris -- how much debris can
4 your body take before your body says enough.

5 Nobody knew what a safe level was then, nobody knew now.
6 And they kept selling this and they kept selling this until
7 ultimately they finally quit.

8 Now, if we go back to the book, please. So that's what
9 we're looking at here.

10 J & J/DePuy, they knew the metal-on-metal wasn't going to
11 work. Not only did they know that, but they also knew they
12 hadn't solved anything.

13 They started selling this product, and they had never
14 tested it with people. They put it in machines. They put it
15 in machines, and most of the time when they put it in machines
16 they put it in a liquid, as opposed to a body. And then they
17 would take that liquid, and in most of their tests in the
18 machines they put it upside down. They put it like -- like
19 you're standing on your head. So it's in liquid and they
20 would do this. And they would do the same motion, back and
21 forth, back and forth, back and forth. And they would just
22 test it in a machine doing that. Never stopping. As if
23 that's the way people walk. You only move your leg the exact
24 same way back and forth. You never go sideways. You never
25 stop and start. You don't climb stairs. You don't look up.

1 You don't look down. You don't sit down. You don't stand up.
2 You don't lay down. You don't get up. And they didn't -- You
3 don't jog. You don't step. They didn't do any of that.
4 Their testing was thoroughly inadequate, and it was never
5 tested in people.

6 Now, a lot of people think the FDA tests these things.
7 Oh, no. The FDA relies upon the manufacturer to test. That's
8 why we sue the manufacture. We don't sue the FDA. So they
9 decided to sell these implants before they ever tested them.
10 And they used a loophole to get by the need of testing with
11 the FDA. You will hear about this loophole. That word
12 loophole, I didn't make that up. The New England Journal of
13 Medicine is my cite, and it's clear they used a loophole.
14 That's what the New England Journal of Medicine pointed is the
15 reason that these have been tragic failures. And they have
16 been tragic failures. These are five cases. There have been
17 thousands of cases. These are the five that are being tried
18 right now.

19 The patients were the unwilling guinea pigs. They didn't
20 even know it. They thought they were paying a premium, paying
21 lots more than they would for poly to get the very best that
22 was out there never having remotely any idea that they were
23 the test subjects.

24 They're the ones that were going -- I mean, the company
25 is just going to sit back and wait and see. "Hey, I wonder if

1 this works." And that's what happened.

2 Now, over time it became apparent the company had not
3 solved the problem. See, the company was keeping track of how
4 many revisions, how many people had to go back in and have
5 their hip exchanged because it wasn't working. And they know
6 what an acceptable amount of revisions are. There are
7 guidelines for this.

8 They knew what the acceptable failure rate was, and you
9 could measure and see what the failure rate was of
10 polyethylene, of the plastic.

11 And so the company starts getting in these failures. And
12 on some of them the company just issues them, doesn't even
13 count them.

14 On others, the company -- I don't know if they misplaced
15 them or whatever, but the company never tells anybody about
16 it. And then the company starts making excuses. Well, we're
17 getting these because some doctors must have messed up. It's
18 really interesting because the doctors were putting in the
19 plastic, too. But the plastic is not failing the way the
20 poly -- the way the metal is. So time shows the real truth.

21 Their Pinnacle metal-on-metal was a dismal failure.

22 I've got a picture up here of what's called the National
23 Joint Registry for England. England and a number of other
24 companies but England is the big one. You want to use the big
25 one for the sample size. Don't go to the little small

1 countries. England has national health insurance. You don't
2 have an insurance company. You don't have to pay. You just
3 go in, and you get treated, and as a result, the government
4 keeps up with everything they're paying for. So there is in
5 England a really good record of every hip that's been put in
6 and how many of them worked and how many of them don't, and
7 every year those results come out. For years and years and
8 years, J & J/DePuy had a man on the inside who was in charge
9 of working on this report. They knew these numbers. They
10 know 'em before the public does.

11 But those numbers show that the Pinnacle metal-on-metal
12 hip is a dismal failure. It just is.

13 So what happened?

14 Well, the truth is through this lawsuit we learned that
15 J & J/DePuy used multiple manipulations to sell this implant.
16 You're going to hear evidence that no one has heard before.
17 You're going to hear evidence about outrageous payments, and
18 even bribes, that were paid to doctors to use these hip
19 implants.

20 They would pay the doctors under a variety of schemes.
21 Some they would say we're paying them because the doctor
22 helped us invent the product, just didn't get listed on the
23 patent.

24 Some they would say -- They would go to the doctors --
25 They did this massive study. It's called a seeding study, set

1 up by the marketing development, not research and development.
2 And here's what they did.

3 They says, hey, doctor, if you will use our Pinnacle hip
4 implant for, say, 50 patients, we'll pay you three, four
5 hundred dollars a patient. All you got to do is send us the
6 results, and let us know how it's going on. We'll call it a
7 study, and you will be in our study. You can add it to your
8 resume; I did a study for DePuy.

9 But what they were really doing is paying the doctors to
10 put in the implants so that the doctors would use 'em. They
11 would just mark up the price so that the patient winds up
12 paying. Or the government -- if it's Medicare -- or
13 insurance, or whatever.

14 That's what they were really doing. In fact, in that
15 study they did an analysis before they did the study. How
16 much would it cost us to pay these doctors like that?

17 Well, it would cost a few hundred thousand.

18 How much would we make off of it by selling the hip
19 implants?

20 We would make a couple of million dollars.

21 Okay. Let's do that one.

22 That's the way this was done.

23 Johnson & Johnson/DePuy, they hid the metal-on-metal
24 dangers, and they used doctors as marketers. They would use
25 surgeons, and they would pay them to come teach the sales

1 force how to sell. They would use the surgeons to write fake
2 articles and put 'em in the scientific literature.

3 Doctors use something called "evidence-based medicine."
4 All doctors use it. It's a term you'll hear because doctors
5 want to make decisions based upon the evidence. So what
6 Johnson & Johnson/DePuy did is they made up the evidence. So
7 the doctors are basing it upon evidence that's just not true.

8 And I will show you these things. I will show you
9 everything I'm talking about. That's one reason it's going to
10 take us about four weeks to put on our case.

11 It is my hope and pledge to you that four weeks we will
12 be done. And that's the end of this week, Your Honor, being
13 one. I know we're off next Monday, I'm even counting that.
14 Four weeks I think I can put my case on if we don't get any
15 hold-ups.

16 But I want to you to hear all this evidence, and I tell
17 you that because Mr. Sarver gets up to speak, and I don't get
18 to tell you anything after he's done. I just get to call
19 witnesses. He may try to suggest things Mr. Lanier can't
20 prove this. One of his favorite words is "outrageous."
21 That's outrageous. But I promise you, everything I'm showing
22 you, I'll show you the evidence. I will show you evidence on
23 all of this.

24 I will show you evidence that Johnson & Johnson/DePuy
25 mounted the world's largest direct-to-consumer campaign to

1 drive their sales.

2 What do we mean by that? "Direct to consumer" means they
3 would advertise about these Pinnacle hip implants to you and
4 me. You can't buy them at the store. You can't go to the
5 store and say: I'd like a Pinnacle metal-on-metal hip
6 implant, please, I'm going to put it in this afternoon. See
7 how it works. That's not the way it's done. Doctors do this,
8 But they were advertising to you and me because they figured
9 out if they did it we would go to our doctor's and say, Man, I
10 want that Pinnacle thing I saw on TV. And they determined
11 that 97 percent of the time the doctors would put in what you
12 asked for. So they're selling you and me and our parents and
13 doctors. I don't know how many of you follow basketball. I
14 know we've got some sports people on the jury. That's coach
15 Krzyzewski. That's an unusual name to pronounce when it
16 starts with a K. So people just call him Coach K. They used
17 that in this massive ad because Coach K who was at Duke
18 University was coaching the U.S. Olympic game. They would buy
19 ad space, and it was a big deal, and they would say Coach K
20 has DePuy hips. He does have DePuy hips, but he doesn't have
21 Pinnacle metal-on-metal. He's got the metal-on-poly hips that
22 they're going to tell you just weren't any good and you can't
23 trust. They just didn't tell the consumers that.

24 Anyway, you will hear all this. You're going to hear
25 their story of deception. You're going to hear their stories

1 of pay-offs. You are going to hear about their hidden truths.
2 You're going to hear about them with the government entering a
3 plea of guilty -- a deferred prosecution agreement, is what
4 it's called, where they have deferred prosecution on the
5 anti-kickback statute. Chris Christy when he was Attorney
6 General, he prosecuted this. And they paid a massive fine and
7 agreed to the government watching them for a year so that
8 they -- and they changed the way they were doing business
9 supposedly because of the accusations of them bribing doctors.

10 So you're going to hear all of that. You're going to see
11 it.

12 And then the consequences. Ladies and gentlemen, their
13 story began to unravel. It began to unravel because the
14 revision rate, failure rate, was so high with these Pinnacle
15 metal-on-metal. It started with a different product they
16 made. They also made an ASR metal-on-metal hip. ASR was a
17 different product. It had some very real differences. It
18 didn't have a cup and a liner. That was all combined. It was
19 slightly different shape. But it was metal-on-metal, and
20 DePuy swore to the FDA that it was substantially equivalent,
21 is the language, to the Pinnacle metal-on-metal.

22 So that starts failing, and it's failing massively. The
23 company decides they're going to re-call it. They should have
24 re-called it a lot earlier. But they drug their feet. They
25 finally re-called it. And when they re-called it, they got

1 all this publicity. It was a massive problem. It was a big
2 legal mess. But the company knew that's okay, we'll just
3 shift people over to Pinnacle. We'll tell the doctors it's an
4 ASR problem, not a metal-on-metal problem.

5 Now, some of Johnson & Johnson/DePuy's hand-chosen
6 doctors begin demanding action saying you've got to do
7 something.

8 Two of these doctors will be in the courtroom by at least
9 video for one of them. That one on the top left is Dr. Tony
10 Nargol in England, and DePuy used to pay him to teach people
11 and give lectures and to go around.

12 And he said this ASR is a failure.

13 They said, no, it's not.

14 He said, yes, it is, and Pinnacle is, too.

15 Finally, this company said, well, yeah that ASR -- we're
16 going to have to pull it, but they fought on Pinnacle, and
17 they said No, no, no, we can't go there.

18 Dr. Black Irving is going to come to court, and you're
19 going to hear his testimony. He's going to tell you
20 everything I told you was true. He was on the inside, and he
21 knows it better than anybody.

22 Sonny Ball is another one who complained. I don't think
23 he'll be in this courtroom.

24 Even at some point Johnson & Johnson/DePuy's highest paid
25 doctors -- These are doctors that are still taking lots of

1 money from the company -- even they quit using the product by
2 2010. They quit using it before Ms. Aoki got hers. They just
3 didn't tell anybody because they were getting a cut off every
4 one that got sold.

5 So once this all starts boiling up, Johnson & Johnson --
6 and Mr. Powell, I respect him a lot, but when he said this
7 case is really just about DePuy -- No. No. No. DePuy is the
8 hand, but the rest of the body is Johnson & Johnson. And
9 Johnson & Johnson outlines the strategy for DePuy. Johnson &
10 Johnson handles the lawyers for DePuy. Johnson & Johnson
11 handles the regulatory for DePuy. Johnson & Johnson oversees
12 and approves the marketing for DePuy. Johnson & Johnson is
13 the person behind all of this.

14 And they outline a strategy for DePuy on what they're
15 going to do.

16 And the strategy is one that we can see as it unfolds.
17 It's really interesting. The first thing the company does is
18 they said, look, metal-on-metal is going away, people have
19 learned it's not working, but one thing we could do, we could
20 pretend we've made a better ball. We'll call it the Asphere
21 head or ball. We'll tell people we've made a better one. So
22 now this one is really going to work.

23 And then all of the people who say metal-on-metal is bad
24 and who are going to quit, they will all come work for us.
25 And they figure out how to maximize every sale they can before

1 they quit selling this product.

2 And when they quit selling it, they were fine with that
3 too, because when yours fails it's not like you can take your
4 car in that's under warranty and say would you fix this,
5 please. When it fails you have to buy another one from 'em.
6 You've got to go pay for a whole other one. And so the
7 company got real excited.

8 The marketing people said, hey, it looked like we were
9 going to lose money but it turns out we're making a ton of
10 money on the revisions. Happy days are back. The market we
11 thought we lost has turned out to be a big boon to our bottom
12 line.

13 And that's what they did.

14 Oh, that doesn't look too good, does it.

15 See, books get typos.

16 Thousands of people have basically a walking time bomb in
17 their hip. There are thousands of people who have this
18 problem. For many, thousands upon thousands, it's means --
19 meant revision surgery. We'll show you those statistics.

20 And for some it will depend on what day it goes off. And
21 I'm sure for some it will probably last them for their
22 lifetime.

23 So that's what we have, thousands of people suffer, but
24 these guys have their cases before you.

25 I'm going to pause, Your Honor, and give the floor to

1 Mr. Cannon and let him talk about these folks a little bit.

2 If I might, Your Honor?

3 THE COURT: Mr. Cannon.

4 MR. LANIER: Thank you.

5 MR. CANNON: May it please the court?

6 THE COURT: Yes, sir.

7 MR. CANNON: Morning. Hope today finds you well.

8 If there are moments -- minutes during this trial that I
9 seem to be burdened, somewhat overwhelmed, somewhat at a loss,
10 I want to share something with you: There's a group of
11 individuals out here that I've grown to know well. I'm their
12 lawyer, I'm their friend, and I'm their advocate.

13 What that means to me is I'm the conduit between these
14 people, what happened to them, and you. And in order to carry
15 their story, their life, their ups, their downs, their
16 victories, their tragedies, in order to carry that to you it
17 has to flow through me. There is a burden there, because I've
18 never been associated with a group in my life, in my
19 experience, and that's getting to be abundant, happens
20 relatively fast, that has as much duty, dedication, service,
21 honor, kindness, as this group of people that stories will
22 flow through me.

23 I feel sometimes like a power-lifter when -- when I'm
24 trying to lift the burden of bringing everything to you about
25 the truth, the truth, the truth of what happened to them and

1 who they are.

2 We've been here for a good while and it's a great
3 opportunity now for me now to introduce these people to you.

4 We have Margaret Aoki.

5 Margaret, if you would stand up, please, ma'am.

6 Margaret is a resident of Austin. She's from Michigan.
7 Her dad was a professor up there. Her mother was a teacher.
8 Margaret had been a lot of places. They had been to Michigan.
9 She had been to Salt Lake City. She lived in Alaska. She's
10 lived in -- and how could they have possibly left out
11 Waxahachie. And she lived in Waxahachie. And now she's back
12 in Austin.

13 You -- you can sit down, Margaret.

14 Margaret was born September the 1st, 1949. She married
15 Richard Aoki, who she met in Waxahachie, where he was a
16 landscape -- landscape artist. And they were married for 21
17 years -- 25 years, until he met his untimely death in Zilker
18 Park having a heart attack, riding a bicycle, after he had
19 survived a tour in Vietnam, been awarded metals in Vietnam,
20 was a Green Beret in Vietnam, survived all that, came home.
21 Ms. Aoki bore him a daughter, lovely daughter, Robin.

22 And in 2006 she lost him. And that's the same year that
23 she got cancer, had chemotherapy. And when I talk about
24 resilience, when I talk about strength, when I'm talking about
25 -- when I talk about people who get bucked off and get back

1 on, that's who -- that's who I represent.

2 She went to a doctor in Austin with her hip. In 2010 --
3 do you remember Mark talking about all these complaints coming
4 in? DePuy was overloaded with complaints about metal-on-metal
5 and they had a doctor named Heinrich in Austin that they had
6 picked to work with and paid him scores of hundreds of
7 thousands of dollars, and unfortunately she ended up with him
8 and he put a metal-on-metal in her in September the 20th of
9 2010.

10 And she had to have to take -- have it taken out in
11 February of 2013, because of the metal-on-metal.

12 These people got -- I'll get to all of 'em -- I'm going
13 to use way too much time going like this, judge. I'm going to
14 speed up on them on --

15 THE COURT: Okay.

16 MR. CANNON: But these people are so great I wish I
17 had a week to talk about them, Your Honor.

18 THE COURT: I can't give you that much.

19 (Laughter.)

20 MR. CANNON: Well, I -- I can talk about 'em a
21 month, to tell you the truth, they're -- they're splendid.

22 She had -- they've got one thing in common. They all had
23 metal-on-metal hips.

24 They got a second thing in common. They all had trouble
25 with their metal-on-metal hip -- a metal-on-metal on hip.

1 They had a third thing in common is they all had to get
2 taken out and put another kind of hip in there besides
3 metal-on-metal, because the metal-on-metal is not any good.

4 That's the reason they had to take it out. That's the
5 reason they didn't put it back in there.

6 And we can look -- paper this courtroom with papers and
7 papers and papers, but don't the facts speak for themselves
8 that you've got five people here, come from all walks of
9 life -- let's go to the next one.

10 Mr. Christopher, my only native Texan. Beaumont; is that
11 Texas?

12 THE WITNESS: Yes, sir.

13 MR. CANNON: Close to Louisiana?

14 Do you have dual residency?

15 THE WITNESS: My wife does.

16 MR. CANNON: Okay.

17 Okay. She's from Louisiana. And Mr. Christopher here
18 was -- you were 46 years old when you had this hip done.

19 You can sit down, Jay.

20 And your wife?

21 Yes. He's got two kids, Blake -- he's got Blake and
22 Trevor. They're in their 20s.

23 Jackie, his wife, and he have been married forever.

24 When -- earlier on when the judge would say we've got eight
25 plaintiffs I'd keep thinking, no, we've got five, because I

1 think of them as one. Because they are one. When I see one I
2 see the other. When one hurts the other one hurts. When one
3 loves that -- when one cries the other one cries.

4 So, to me, his case is her case, her case is his case,
5 because that's what they are. He's been fortunate enough to
6 live in Beaumont and work in a small electrical supply
7 business and do electrical work with his dad, who's now 83
8 years old. And his dad is enheartening to me and encouraging
9 to me because he homeschools a grandchild. He's 83 years old.

10 So when they say this guy is about to play out or there's
11 not much left, there's a lot left to homeschooling a child,
12 isn't there?

13 Okay. Christopher Greer.

14 Dr. Greer -- can you hear me, Dr. Greer?

15 Dr. Greer and I have something in common.

16 Dr. Greer, is your wife Jane here with you?

17 Thank you.

18 Dr. Greer is another individual born outside Texas and --
19 you can sit down Dr. Greer.

20 Can you hear me?

21 There you go.

22 Dr. Greer is a plastic surgeon. He grew up in Chicago.
23 And he moved to -- he's lived in Colorado. He lived in
24 Florida. He went to Vietnam. He was in the Navy. He went to
25 medical school. He had three kids: Stephen, William --

1 Stephen is here. William is in Austin. And Don, Jr., is in
2 the Air Force -- Army. He's in the Army. And he has three,
3 four, five Bronze Stars, something like that, in Afghanistan,
4 and we thank you.

5 And his son Stephen, he adopted.

6 His son William was hit by a car when he was a teenager
7 and he's blind and had some frontal lobe damage. And, you
8 know what, these people's response to that? You talk about
9 getting back on the horse, they went and adopted a child that
10 was supposedly -- had -- the only way at their age they could
11 adopt a child is to say we'll take someone with something
12 wrong with them, a special needs child. And that was their
13 response to their child getting brain damaged.

14 So they went and got another one with special needs and
15 there are absolute miracles that occur in front of all of us.
16 There's nothing wrong with him. They were wrong. The child
17 was absolutely normal, the one they adopted when they thought
18 he had special needs.

19 Dr. Greer showed up in Vermont with him in the car and
20 totally surprised Jane. She didn't even know there was a baby
21 coming: Here he is, go look in the car.

22 Dr. Greer went to -- he's active. He road, he rides
23 horses. He completes riding horses. He works on a ranch,
24 built a fence. He's a plastic surgeon and he's a very, very
25 kind man. And his wife will not testify in the case, and

1 we'll explain that to you. There's conditions and things that
2 happen that just prevent that -- from perhaps her being able
3 to do that from a physical standpoint but that doesn't mean
4 that she's not here and a big part of him and his life and
5 what's going to happen.

6 He had his hip put in, in San Antonio. It was put in by
7 Dr. Goletz.

8 Let me stop here. It's important.

9 I skipped Christopher. I skipped Aoki. I was about to
10 skip Greer to tell you something really important. This is --
11 this is me, I'm the conduit, what I want to bring you the
12 truth. I'm going to bring you every word I can from the
13 doctors who treated these individuals, the ones who did the
14 surgery, not someone that we looked up that's a professional
15 witness or writes books or whatever, the doctors who looked at
16 the hip, looked at the damage, and saw what was actually in
17 the operation. They don't have to go back and look at a
18 record, a film, or make an interpretation. They were there
19 and they did the work.

20 His doctor is Dr. Morrey. That's who did the revision of
21 his hip when it had to come out. And Dr. Morrey I think you
22 will find extremely interesting. He's Mayo trained. His dad
23 is Mayo trained. His dad operated on the President of the
24 United States. They are eminently qualified to give their
25 opinions.

1 Dr. Kearns, you were lucky to get him, Mr. Christopher.
2 Dr. Kearns, a 65-year-old doctor in Houston who is with --
3 with the largest orthopedic group in Texas, second biggest
4 customer of DePuy. He says that the hip is -- that
5 metal-on-metal is no good. He wishes he had never heard of
6 them. He wishes he could take them all out. And he'll be
7 here to testify. That's -- he was lucky to get him because
8 when he started having trouble with the metal-on-metal Mr. --
9 Dr. Kearns didn't hesitate, didn't try to hide it, didn't
10 blink, said we got to get that thing out of you, because if we
11 leave it in there it eats you up.

12 With that -- you will get to see what this metal does.
13 It's cobalt, that's a heavy metal. Chromium is a heavy metal.
14 It gets out of there because that rubbing, metal-on-metal, the
15 lady that was sitting out here that farms, is probably home
16 now greasing a disc now because she's going to get in season
17 because she knows that you can't leave those bearings
18 metal-on-metal without burning her bearings up and ruining the
19 disc. She knows that. And I know that. And you know that.
20 And you can't sell a product that's metal-on-metal and put it
21 in somebody's body and expect it to work.

22 Hello? Don't just do that for money. I think that's
23 what we'll prove.

24 We've got Greer.

25 What about Klusmann?

1 Where is Mr. Klusmann?

2 Dick.

3 Susan.

4 Mr. Klusmann was the CEO of a -- well, he's not from here
5 either. You've only been down here, what, 30, 40 years.

6 (Laughter.)

7 MR. CANNON: And he's from Wisconsin.

8 Susan is from Wisconsin.

9 He went to Madison for a while, played football. Then
10 they went to Milwaukee. She taught school up there. She's
11 going to want to tell you the story about when they first met
12 and he got in his football uniform and took him to the
13 classroom where she taught in the inner city and she took him
14 in his football uniform to show him to the kids and have him
15 tell them about football.

16 Thank you.

17 They got bucked off several times. They got back on.

18 Dick's managed a hospital there in Austin for a long
19 time, St. Mary's. It's got about 150 beds. They had
20 Jennifer, who lives up here in Dallas. And Jennifer's got
21 three kids.

22 And then they had Mindy, about two years later. And they
23 found out that Mindy has spinal muscular atrophy, which is
24 terrible. None of your voluntary muscles work. And she was
25 supposed to live until she was five years old and that would

1 be the end of it. He worked in the hospital. He talked to
2 doctors. He read books. And the two of them developed a way
3 to treat her, a physical therapy. She's still alive. She's
4 married. They've got a grandchild that she adopted in China.
5 They went to China. And it's just amazing how the Lord pulls
6 these things through. It's just absolutely -- there's a lady
7 that's supposed to have died when she's five years old, she
8 works, she's married, she's disabled, and she's picked a child
9 up that nobody else wanted and is taking care of it.

10 You see my burden?

11 You see -- just incredible stories.

12 He unfortunately went to Dr. Heinrich. Dr. Heinrich put
13 two hips in him. Dr. Heinrich had to take two hips out of
14 him. But he waited a long time. And the tissues got
15 literally eaten up. He's got -- he's had five surgeries. The
16 last one they tries to revise the hip and there's two tendons
17 they couldn't even sew back, they're just gone. They couldn't
18 operate the hip. That man right there tries to walk a mile
19 and a half every day. I'd hate to walk a mile in his shoes
20 with what he must feel like.

21 You know what they did when they found out that Mindy had
22 spinal atrophy, spinal muscular atrophy?

23 Immediately they went and adopted a child, with special
24 needs.

25 You know, these are not people that sit down and feel

1 sorry for themselves that I've represented. These people are
2 people that get up swinging to do the right thing.

3 Last, but not least, Captain Peterson, Karen. Captain
4 Peterson is from Pennsylvania. You ever heard of Slippery
5 Rock, Pennsylvania? He was an all American swimmer there. He
6 won the nation in swimming in the 50 and the 100.

7 MR. PETERSON: That's right.

8 MR. CANNON: You okay, Captain?

9 Have a seat. Karen.

10 How much time I got, Your Honor?

11 THE COURT: You've got about 20 minutes.

12 MR. CANNON: Captain Peterson. You know, I got a
13 preacher I just dearly love, and he says the good sermon is
14 when you tell 'em -- tell 'em what you're going to tell 'em,
15 tell 'em and then tell 'em what you told 'em.

16 Some of this stuff I feel like if I tell you now, you'll
17 think that's not true. I mean, that can't be true. I mean,
18 this is like -- this is like a book. I'm not a party to this.
19 I can't imagine I'm seeing this. That's the way I feel now.

20 But I need to tell you what he's going to tell you
21 because this guy is so modest. Well, you know people that are
22 kind of marginally good that brag on themselves?

23 You know people that are good that brag on themselves?

24 This guy doesn't brag on himself at all. And it kind of
25 makes him mad if I brag on him.

1 But if I don't brag on him -- That's my job.

2 And I'm going to brag on you.

3 He got out of school and he was in the 2nd Navy SEAL
4 team. He went through the SEAL training and in 1961 -- about
5 1964, he did his first three tours in Vietnam, most of the
6 time behind in enemy lines. He would shoot a gun, carry a gun
7 that's the same kind the enemy carried because when he fired
8 his gun he wanted them to think he was one of them because he
9 was in their area.

10 His wife, Karen, bore him three children -- bore him
11 Eric, and then they got two grandchildren, Anna Elise, named
12 after both mother and the grandmother. That's politically
13 correct. And Jack, Jack William, the middle name of his
14 grandfather. And there's things -- I wrote down to say about
15 him that he's courageous and he's brave. It's not true. He
16 got the Silver Star for valor. Valor is a step above courage
17 and bravery. It's my honor to know him. It's such a special
18 privilege and honor to represent him, not that he's a step
19 above any of these other people, not that his damages or his
20 pain is greater or his disability is greater, but I just feel
21 so overwhelmed by speaking on behalf of him because of what
22 he's done for that over there (indicating).

23 He went to -- I'm not sure he even wants to testify about
24 it because he doesn't want his grandchildren to know that with
25 his medal -- his silver star -- with his Silver Star -- I

1 think it was -- Let's talk about this. Let's talk about this
2 first.

3 While he was over there Karen had his child in Mumbai
4 India? No? Virginia. If you notice every once in a while it
5 doesn't click, and they have to give me a clue, Virginia
6 instead of India. And the later they moved to Mumbai, India.
7 And if you notice every once in a while they have to give me a
8 cue that's it's Virginia instead of India.

9 He's worked in Antarctica.

10 You know what the hardest thing that ever happened to him
11 is? What he had to go through with this hip. Harder than
12 Vietnam, harder than Navy training, harder than SEAL training,
13 harder than Antarctica because of what that heavy metal did in
14 his system and the way he felt. You know, I find Captain
15 Peterson to be credible. I believe every word he said.

16 I bet that was hard to be over there and have that baby
17 born and him be in the jungle behind the lines?

18 Can you imagine?

19 And then thinking: I've got to stay alive. He said it
20 was easy before then, but it was hard after the baby, because
21 he had to get home to him.

22 And he is his son's hero, but it's not because of that
23 Silver Star. It's because of the rest of the way he's lived
24 his life, honorably and with integrity. His whole life has
25 been valor. And I really thank you for your service, Captain.

1 It's my honor to know you and to speak for you.

2 He had to go behind -- he didn't have to. The enemy had
3 captured a -- I'm about through. The enemy had captured one
4 of our soldiers, and they knew they were going to torture them
5 pretty bad.

6 You okay, captain?

7 MR. PETERSON: Sure.

8 MR. CANNON: And so he and five other guys went in
9 at night to get the guy out, and they got discovered in there,
10 and they got in a fire fight. And there were 500 Viet Cong,
11 and there were six of them.

12 They didn't find the guy. Whatever happened to that poor
13 soul, bless his heart, rest his soul, but Captain Peterson got
14 himself and the other five SEALs that he was leading out of
15 that camp with 500 Viet Cong and killed scores of them,
16 many -- And this hurts him. He doesn't want his grandkids to
17 know about it -- many with his own hands. For me.

18 His doctor will testify. Dr. Heinrich, will testify by
19 deposition -- by deposition. Now, you can tell I like these
20 guys. Can you tell that?

21 I like 'em all. I love 'em all.

22 What I'd like to know, they got your product put in. It
23 had to be taken out. Can you give them for one time, one day,
24 one minute, an honest answer of why you had to endure this, go
25 through this again, risk having more revisions, more

1 surgeries, more limitations. Because every time you cut on
2 that again, you got less chances of a good result. You've
3 made these people vulnerable. You have hurt them. Give them
4 a real, honest, straightforward answer of why this hip failed
5 in them and promise 'em you won't do it again, you'll try
6 harder. They deserve that.

7 May it please this Court.

8 MR. LANIER: Your Honor, may I finish?

9 THE COURT: Yes.

10 MR. LANIER: And I've got about five minutes or so?

11 THE COURT: I think that's right.

12 Ronnie, help.

13 MR. LANIER: I've got it, Ronnie. Took me a minute.

14 Ladies and gentlemen, you're going to hear -- Let me turn
15 my mic back on.

16 You're going to hear from a lot of different witnesses.
17 One of the key witnesses I want you to wait for -- and we're
18 going to have to bring him live -- is the doctor behind three
19 of these patients. His name is Matthew Heinrich.

20 Dr. Heinrich had a lot of these patients and had a lot of
21 problems with them. And so while his patients were filing
22 their cases, DePuy hired Dr. Heinrich behind their back to be
23 their -- their expert in this case.

24 And then the DePuy lawyers sent me a letter, an email,
25 telling me that the patients were no longer allowed to talk to

1 their doctor because their doctor worked for DePuy and that I
2 was to instruct them that they were not allowed to talk to
3 him.

4 And what the patients didn't know is their doctor had
5 been working for DePuy for years.

6 When Dr. Heinrich got out of medical school -- and he
7 went to Texas Tech Medical School. When he got out of medical
8 school, he tried to open his own practice, without anybody
9 else, down there in Austin. And he quickly was latched on to
10 by Johnson & Johnson/DePuy, and they said we'll give you
11 patients, we'll help -- we'll funnel you patients if you will
12 do our bidding.

13 So DePuy set up this -- Johnson & Johnson/DePuy set up
14 this web site, "Hi preplacement.com," and you said here's my
15 zip code I need a doctor. You punch it in. If you are in
16 Austin, you get Dr. Heinrich. DePuy is paying him the whole
17 time without you knowing it. They're paying him for different
18 things, and you will hear about it. And then they start
19 paying him to be an expert to testify.

20 You're going to get to meet him. But even he can't say
21 that he messed up or what went wrong with his patients or the
22 others.

23 And so we come here today with a simple question, and
24 I'll leave this for Mr. Sarver, but for Ms. Aoki and
25 Mr. Christopher and Dr. Greer and Mr. Klusmann and Captain

1 Peterson, why did their hip fail?

2 And Mr. Sarver can write his answers on here, and then
3 we'll look at them during the trial. We'll go back to the
4 flow because the answers are not going to hold up. I've been
5 listening to 'em.

6 The answers just aren't -- aren't -- aren't good.

7 You see, Johnson & Johnson outlined the strategy for the
8 company. They said here's what you need to do: Get the
9 lawyers and do the following; first of all, just try and show
10 that the product is -- is good. Use different registries,
11 play with the numbers, find somebody somehow that is looking
12 at such a limited scope of vision that they think it's okay.
13 So first of all, just try to play with the numbers.

14 And if that doesn't work, then you need to blame the
15 victim. Say, oh, they did too much on their hip or, oh, they
16 just have an unusual body.

17 When Mr. Powell said allergies, I'm going to find it real
18 hard to believe but if they think that these people are just
19 allergic -- Mr. Klusmann isn't allergic -- if they're going to
20 argue that these people are allergic to their metal-on-metal
21 hip implants, then let them write it down, if this is
22 allergies. It's not allergies.

23 If they're going to argue that they have got some
24 mysterious disease, let them write it down.

25 What -- let's have a record of it and we'll work through

1 the trial on it because that's the way the -- Johnson &
2 Johnson said to defend. They said use funny math. They said
3 blame the victim -- or blame the doctor.

4 You know, if you want to say, oh, it's the doctor's
5 fault, then write it down, the doctor messed up.

6 I want to tell you with each of these people, all they
7 had to do to fix their problem -- those doctors had to pop out
8 the metal liner, put in a plastic one. Problem fixed.
9 Because what their body did is what most bodies will do; it
10 reacted to the metal poison.

11 So I look forward to having them fill this out.

12 Your Honor, I look forward to trying this case in front
13 of you, and thank you that you let us do it.

14 Thank you, ladies and gentlemen.

15 THE COURT: Mr. Sarver, you need a break?

16 MR. SARVER: I think it's a good idea, Your Honor.
17 Yes. Yes.

18 THE COURT: Okay. We'll take another quick break,
19 ladies and gentlemen.

20 Don't talk about the case.

21 THE SECURITY OFFICER: All rise.

22 (Recess taken at 10:41.)

23 (Outside the presence of the jury.)

24 THE COURT: Outside the presence of the jury but on
25 the record Mr. Powell has a motion.

1 MR. POWELL: During the opening statement Mr. Lanier
2 referred to the deferred prosecution agreement and explained
3 his version of the deferred prosecution agreement. That is an
4 inadmissible thing to talk about in this case. It has not
5 been offered into evidence. It is clearly a violation of
6 federal rules of evidence 401, 403, 404, 408, and 410.

7 Also during the opening statement he told the jury there
8 are thousands of more cases, which is also irrelevant to the
9 outcome of this case. And it violates federal Rule 401, 403.
10 And we think that was a highly inflammatory and improper thing
11 for him to say.

12 We move for a mistrial at this point in time because of
13 the improper putting into the jury box of those two very
14 inflammatory, inadmissible facts.

15 THE COURT: Motion denied.

16 MR. SARVER: Your Honor, before the jury comes in,
17 given what they said about thousands of cases it seems to me I
18 have every opportunity to talk about the lawyer advertising
19 that generated the thousands of cases.

20 THE COURT: Remind me, is that in our in limine?

21 Let me look. Let me look.

22 That's number 2.

23 (Pause.)

24 THE COURT: You can certainly talk about the cases.
25 How does that bring up the advertising?

1 MR. SARVER: Your Honor, the reason that there are
2 thousands of cases is that there has been millions of dollars
3 of lawyer advertising.

4 If they can talk about the numbers, I've got to be able
5 to talk about how did the numbers grow.

6 THE COURT: Any response?

7 Mr. Lanier, any response to that?

8 This is number 18 and 19, and I think 3 -- no, 2.

9 MR. LANIER: Yeah, I don't think they have got any
10 witnesses that are going to say it was lawyer advertisements
11 that were the cause.

12 MR. SARVER: Oh, Your Honor, we do. We actually
13 have expert witnesses who have written reports that say
14 actually that.

15 MR. LANIER: If they're going to call -- if they're
16 making a representation right now on the record that that
17 witness will actually show up in this courtroom then I'll move
18 the argument, but I'm going to be shocked if they will make
19 that representation on the record that they're going to bring
20 the witnesses.

21 MR. SARVER: We absolutely will bring witnesses that
22 will testify to that. They will -- whether we'll bring -- if
23 you're referring to Dr. Barsky, who is the witness from Boston
24 who has written the report, there certainly will be
25 witnesses -- experts who rely on Dr. Barsky's report that will

1 testify in this case. Absolutely.

2 MR. LANIER: Then they're not going to have any
3 testimony from a qualified expert that the advertisements --
4 and the reason it takes an expert is because there are so many
5 other things it could be. It could be the write-ups in the
6 New York Times. It could be the news accounts. It could be
7 all these other things, the ASR re-call, all these other
8 things, advertisements for other type of hip implant cases
9 where people didn't know what kind they got.

10 I mean, they've got to have an expert to offer the
11 evidence. And I don't think they will.

12 THE COURT: Don't throw the ball.

13 MR. SARVER: I'm sorry.

14 THE COURT: Are you or are you not going to bring a
15 witness that's going to -- that is an expert on this
16 advertisement, not somebody who relies on it, expert on those
17 advertisements?

18 MR. POWELL: Your Honor, our position is that the
19 experts who will --

20 THE COURT: I didn't ask your position.

21 Are you going to bring that actual witness that --

22 MR. SARVER: We are going to bring witnesses who are
23 qualified.

24 THE COURT: No, can't do it.

25 MR. SARVER: Okay. Thank you, Your Honor.

1 Does that preserve our objection for the record?

2 THE COURT: You're a big lawyer, big boy. You know
3 that one way or the other. That's up to you. You make
4 whatever objection you want to.

5 MR. SARVER: All right.

6 Your Honor, I object to your ruling denying our
7 opportunity to respond to Mr. Lanier's opening statement with
8 prove of advertising.

9 THE COURT: That's great.

10 MR. SARVER: Thank you.

11 THE COURT: You think that preserves your record,
12 yes or no?

13 MR. SARVER: Your Honor, I'm no -- no appellate
14 genius. I hope it did. I'm certainly trying to preserve it.

15 THE COURT: Well, I think you're being paid a lot to
16 be an appellate genius.

17 All right. Her we go.

18 I wouldn't suggest you spar with me any further,
19 Mr. Sarver.

20 MR. SARVER: I'm sorry, Your Honor, I didn't mean
21 to.

22 THE COURT: I think you did.

23 (Jury enters the courtroom.)

24 THE COURT: All right. Y'all be seated.

25 Mr. Sarver.

1 MR. SARVER: May it please the court?

2 THE COURT: Yes, sir.

3 MR. SARVER: Thank you, Your Honor.

4 Good morning, ladies and gentlemen.

5 You have in fact heard a story. I'd like you to hear the
6 rest of the story. There is a lot more to it.

7 Every day around the world there are human beings,
8 patients, who are diagnosed with serious and debilitating
9 diseases. They go to their doctor and they will often ask two
10 questions: Can you help me; and what are my choices. What
11 are my choices. Whether it's a cancer drug, a heart stent, a
12 heart valve, a knee or a hip or a shoulder. They want options
13 applications.

14 And they're counting -- Americans are counting on our
15 medical system to provide the choices that can make them
16 better. And fortunately they have those options. But where
17 do these devices come from?

18 They sure don't come from lawyers, either for the
19 plaintiffs or for the defendants.

20 Who invents them?

21 Who designs them?

22 Who manufactures them and produces them and puts them
23 into the hands of doctors?

24 Who does that so that we all have the benefit?

25 DePuy has been doing that for over a hundred years. And

1 I -- I am extremely proud to represent the men and women of
2 DePuy who get up in the morning, they go to work every day
3 with one goal in mind: To produce products that help people
4 to get better, that produce products that allow doctors to say
5 yes to both those questions. Yes, I can make you better; and,
6 yes, you have choices.

7 This is what's called a product liability case. It means
8 that the plaintiffs have sued DePuy saying our product is
9 defective and that some defect in our product caused each of
10 these plaintiffs to have the revision that you've heard so
11 much about already. A "revision" means you redo at least part
12 of the surgery. You do it again, you replace the part. Like
13 Mr. Lanier talked about, you -- you pop out one part of the
14 device and pop in another one. Vast majority of cases on
15 revision go just fine.

16 DePuy doesn't just make hips. They make devices that do
17 many things. They are composed of really marvelous people.
18 And I absolutely respect Mr. Cannon's deep respect for his
19 clients. I have it, too.

20 But the people of DePuy are good people and they go to
21 work and they do build products. And they've been doing it
22 for a hundred years.

23 Ezra DePuy started this company in Indiana over a hundred
24 years ago in 1895. And you don't stay in business for a
25 hundred years making bad products. DePuy doesn't.

1 Even the doctors that they will call in this case use
2 DePuy products to-date and have been for a long, long time.

3 Now, one of the things you know is you're going to hear
4 from some of the DePuy people. The first one you'll hear from
5 is someone that Mr. Lanier asked to come. His name is Andy
6 Ekdahl. He was the former president of DePuy. And he is not
7 a scientist. He's not a medical doctor. He is a businessman.
8 And because of that he will know the answer to some of
9 Mr. Lanier's questions, but not a lot. And, in fact, he's a
10 bit of a quirky person, but he agreed to come because
11 Mr. Lanier asked him to, so he'll be here.

12 How do we know that the device is not defective?

13 How do we know?

14 You're going to hear evidence throughout the trial about
15 what happened. But the easy part is did it break?

16 No.

17 Did it crack? Did it fracture? Did it seize up? Did it
18 stop working?

19 The answer to that is no.

20 We know it did in fact reduce and eliminate pain for
21 years in these plaintiffs. It restored the ability to move.
22 We know this because that's the evidence.

23 And, in fact, you're going to hear that one of the
24 experts actually was provided with four of the explanted
25 devices from these plaintiffs. They were taken out of their

1 body and sent to a laboratory in California. And you're going
2 to hear from a Dr. Patricia Campbell.

3 Dr. Campbell has devoted her entire professional career
4 to something that is pretty remarkable. She has studied
5 explant -- sorry -- explanted devices taken from humans to
6 figure out what works, what doesn't work, and what went wrong,
7 what didn't go wrong.

8 And she will tell you -- she will tell you that the
9 devices in these cases, they were in the hips, they're minding
10 their own business, performing as they were intended and
11 designed to perform. They were not defective.

12 In responding to Mr. Lanier's question and Mr. Cannon's
13 question, absolutely. The very first thing we want to do is
14 to tell you why, why were these five patients revised.

15 At the outset these are remarkably talented, impressive,
16 decent -- they're great people. There is nothing that I say
17 or any one of our witnesses will ever say to say anything
18 against the five plaintiffs. They're good people. But
19 they're all different.

20 Now, that's important. They are different. And the
21 reason for their revision is different in each and every one
22 of these plaintiffs. Very different.

23 If we take a look, Mrs. Aoki -- now, you're going to
24 learn that Mrs. Aoki had her device in the very shortest
25 period of time, but you're also going to learn that she had

1 the very largest amount of wear from her device.

2 How come? How come?

3 Well, the reason is she had something called instability.
4 The tissues and muscles her hip didn't keep the device in
5 place. And she will talk about that on the stand. She'll
6 tell you. She will tell you it clunked, it squeaked, and it
7 felt unstable from the beginning, had nothing whatsoever to do
8 with the design of the device or the fact that the device was
9 metal. A plastic, ceramic, or a device made out of wood would
10 have been unstable, too.

11 So remember the test, remember what you have to do. They
12 have to prove that some defect in our product caused the
13 plaintiffs' revisions. It didn't in Mrs. Aoki. It was
14 instability.

15 Mr. Christopher, another -- and, I'm sorry, Mrs. Aoki is,
16 talented in many ways. You're going to learn she's a talented
17 musician.

18 Mr. Christopher is also accomplished. He owns his own
19 business, an electrical business. And what you're going to
20 learn is that he had hip pain for a long time, but the reason
21 for his revision had nothing to do with his metal device. He
22 had something you can have, I can have, all of us can have
23 depending on our activity. He had bleeding in his hip. It's
24 called a hemarthrosis. It's relatively common. And you don't
25 have to have a hip device to have hemarthrosis.

1 Now, when you bleed in your hip it causes pressure. It
2 causes pain. It feels bad. Most of the time if you wait
3 and -- and -- and stay off it long enough it'll go away, or
4 you can do something called an aspiration and take the blood
5 out of the joint. All that would happen. But it had nothing
6 to do with whether he had a metal device, a plastic device, or
7 some other kind of device. So they are simply unable to prove
8 what they must prove. No defect caused his revision.

9 Dr. Greer, a talented plastic surgeon, well-respected,
10 and I learned more about him today, clearly a very, very
11 decent man. But his revision wasn't caused by metal. He had
12 over his lifetime a fairly rare autoimmune, an autoimmune
13 disease that led to him taking steroids and the steroids
14 caused him to need a hip revision. And we'll talk about that
15 in detail later.

16 What happened is the autoimmune disease called a sarcoid
17 in his hip. It's a -- a packet, a pocket of inflammatory
18 tissue that can cause pain.

19 When that was taken out his hip was fine. Had nothing to
20 do with metal, had nothing to do with the design of the hip.

21 Now, remember, their burden is prove defect caused the
22 revision. It didn't.

23 Captain Peterson, an utterly remarkable human, someone I
24 would be proud to know. Wish I could talk to him. I can't.

25 Thank you. Thank you very much for your service.

1 You know, he's a remarkable man in many ways. What
2 you're going to hear is he's an accomplished athlete,
3 world-class athlete and he wore out his joint. He wore out a
4 hip. He Wore out a shoulder. He wore out a knee. He had
5 them all replaced. Didn't stop him. But he had pre-existing
6 cysts in something called the acetabulum.

7 And the acetabulum is the bony part of your hip joint.
8 Now, he had cysts there before he had hip surgery. Before.
9 And those cysts formed -- and he happens to be a cyst former.
10 He forms cysts in other part -- parts of his body, too.

11 But the cyst form, and he had osteoarthritis. He needed
12 a hip. The cysts were taken out of during his hip surgery, as
13 they should be, done right. But after six years of hard,
14 strenuous work, world-class athlete work, the cysts came back,
15 not because it was metal but because he was pressuring the hip
16 in a way that caused his body to do what it does. It forms
17 cysts. They were taken out by Dr. Heinrich, who did a
18 beautiful job. And he's fine.

19 Mr. Klusmann is absolutely the one patient in this
20 case -- plaintiff in this case who had an adverse reaction to
21 metal. No question about it. He had what's called a delayed
22 type IV hypersensitivity reaction to metal. The best example
23 I can give you is to penicillin. Is a drug that has cured
24 millions of people around the world, but if you are one of
25 those people that reacts badly to penicillin, it can cause

1 serious injury or death. It turns out that Mr. Klusmann is
2 one of the people who has a reaction to metal debris. He did
3 react badly. No question about it. He was revised three
4 times, as Mr. Lanier said. It is something that is
5 predictable. It is a known and expected risk. It is part of
6 your risk benefit analysis when you choose the kind of hip you
7 get.

8 And of all the plaintiffs, he is the one most capable of
9 consenting, choosing, and understanding because he's been in
10 the medical field his entire career. He was the CEO of a
11 hospital.

12 Now, let's talk about hips.

13 What you're going to learn is that the hips we were born
14 with are lined with cartilage. It is -- It's remarkable. It
15 is a wonderful shock absorber. More -- more -- It has the
16 best lubrication properties of anything that has ever been
17 seen. We can't beat it with anything that mankind has
18 developed as of 2015. Your cartilage is an utter miracle.
19 The folks at DePuy are humble enough to know they can't make
20 any kind of hip as good as the hip you were born with. They
21 can't do it. They try every day to make a better hip. And we
22 hope for your children they will offer a hip that's better
23 than anything available today in 2015. But we're not there
24 yet.

25 So what happens when the cartilage wears out?

1 Osteoarthritis is a disease that kills the bone and the
2 cartilage in your joint. You wear it out. The bone becomes
3 spurred, it becomes roughened, it becomes very, very painful
4 because you have bone rubbing on bone. Now, that might not
5 sound painful, but when you walk every step with bone rubbing
6 on bone -- there are lots of nerve endings -- it's incredibly
7 painful. That's what four out of five of these plaintiffs
8 have. I say four out of five because remember all of these
9 plaintiffs are very different. They're very different in
10 terms of their diagnosis, treatment and the reason for their
11 revision. It's not as simple as the plaintiffs would have you
12 believe.

13 Now, four out of five of these plaintiffs had
14 osteoarthritis. Those four didn't include Dr. Greer.
15 Dr. Greer had a different disease. Greer had avascular
16 necrosis. That's a disease where the blood vessels are cut
17 off from the bone, and the bone dies. That's the femoral
18 head, and the femoral head is the top of your femur bone.
19 When that dies, it collapses. When it collapses, it causes
20 tremendous pain. Why did it collapse in Dr. Greer? It
21 collapsed and died because he had an autoimmune disease that
22 his doctors treated properly with steroids. Now, steroids do
23 wonderful things, but they have risks, and those risks are
24 understood and known. And the fact that the steroids taken by
25 Dr. Greer caused his avascular necrosis doesn't make the

1 steroids defective. It's a known and expected complication in
2 order to get the benefits of the steroids. But that's why he
3 was implanted with a hip.

4 Before their hip replacement surgery -- Can you read
5 that?

6 Is that good enough that you can read?

7 Before their hip replacement surgery, all five of these
8 plaintiffs were in severe, serious ongoing unrelenting pain.

9 Here are some quotes from their medical records.

10 With Mrs. Aoki you can see her pain caused her to have
11 pain, caused her to have pain when she walked. More
12 importantly, it caused her pain at night, night pain. She's
13 not even moving. She's trying to sleep at night, and the pain
14 is so severe it wakes her up at night. That's the pain that
15 she was suffering.

16 Mr. Christopher had this hip pain since he was in his
17 teens. It had limited his activities. He was suffering
18 increased pain with everything he did.

19 Dr. Greer really had -- I -- I think one of the saddest
20 onsets, the way he told -- told it to his doctors, if he uses
21 his crutches, and is very good, he gets relief of pain. Now,
22 that's no way to live. And he decided he wanted -- he's tired
23 of living with the pain, and he'd like to get better.

24 And Captain Peterson told it beautifully as well. He
25 talks about being barely able to walk. This is a man who runs

1 and wins triathlons, who wins long-distance bicycle races, who
2 wins international rowing competitions. He could barely walk.
3 He retired sort of from the Navy after 30 years in the Navy
4 and was working a farm and worried about having to give up --
5 ranch, I'm sorry -- worried about having to give up the ranch
6 because he couldn't do what it took.

7 And he couldn't exercise to stay not just healthy and fit
8 but happy.

9 Mr. Klusmann, his pain was pretty much constant, and it
10 started in the '60s. Total hip surgery can make that better.
11 And it did. But it's not perfect.

12 Total hip surgery, and you're going to hear it called
13 arthroplasty at times, THA, total arthroplasty, that means
14 replacement of the hip joint. It has risks, complications and
15 limitations, but it's a risk/benefit. Are you willing to take
16 the risk in order to get rid of the pain. And that's the
17 choice, for all -- all of us.

18 What you're going to learn is that there are really
19 relatively few reasons for hip surgery avascular necrosis,
20 osteoarthritis, you might break your hip, have it crushed in
21 an accident. There might be others, but there are very few
22 reasons to have hip surgery, but there are a lot of reasons
23 why hip surgery is revised or redone. Many reasons.

24 And here is a list of just a few of them. And the
25 reasons there are so many reasons, this is hard. Hip surgery

1 is an amazing surgery, but a lot of things have to go right in
2 order for it to work.

3 It has to grow into the bone. It has to stay in place.

4 It has to be put in at the right angles. You have to
5 have your tissues be tight enough so that the hip stays where
6 it's supposed to be. You have to not reject the device
7 because the body doesn't like something foreign put into it.
8 We all know that. You get a sliver in your thumb. If you
9 don't get it out, what does it do? It's red, inflamed. The
10 body is trying to reject it.

11 Revisions happen. They're a fact of life. There are
12 thousands of revisions every year in the United States for a
13 lot of reasons. Revisions are not rare. Revisions are in
14 fact common. They're routine. They're expected. They're
15 warned about. Every one of these patients was warned about
16 the potential for a revision before they had the surgery. It
17 is part of the bargain.

18 Why?

19 Why then do it?

20 Because the pain is unrelenting. And medical science has
21 found that you're going to get worse if you don't do something
22 about your hip.

23 You heard Mr. Powell in opening statement. You've got
24 choices, but one of the choices -- a long time ago your only
25 choice -- was to sit on that rocking chair on the porch and

1 stop doing the things that make life worth living.

2 That's the reason to do -- to take the risk of hip
3 surgery.

4 Unfortunately, 1 out of 4 of us is going to develop
5 serious osteoarthritis in our hip by the time we're 85.
6 Assuming we make it to 85. It's a very -- it's the leading
7 cause of disability in the United States. And over a half a
8 million people in 2011 underwent total hip surgery. It is a
9 marvelous surgery that has risks along with it.

10 It does confer both the -- the relief of pain, but what
11 also happens is that you're able to move again, and you're
12 able to be healthy, and your life span is actually increased
13 if you elect hip surgery as opposed to those patients who say,
14 no, I'm not going to do that, I don't want to do that.

15 Again, back to Captain Peterson, because we have some
16 information in a document from Captain Peterson that says it
17 better than I could ever say it, "By the year 2004, I could
18 barely walk and could no longer do the work needed on the
19 ranch and could not exercise physically to stay fit, healthy
20 and happy. "

21 Hip was so painful it was difficult to sleep. Like
22 Mrs. Aoki. The problem on the two joints was so limiting that
23 without some correction I faced a future of pain and physical
24 limitation forcing me to give up the ranch.

25 Better than I could say it. That's why he chose to take

1 the risk.

2 In fact, Captain Peterson chose to take a bigger risk
3 than the other plaintiffs because at the same time he had his
4 lift hip replaced, he had a knee replacement also with a DePuy
5 product. At the same surgery. Something that is normally not
6 done because it is more risky. But he wanted to get back to
7 his active life and was willing to accept that level of risk.

8 The plaintiffs did in fact dramatically improve.

9 These are their own words from their medical records.

10 With Mr. Christopher, he had his hip replacement in for
11 six years with no pain whatsoever. This is great. He had had
12 pain since his teens, and now even though he's doing physical
13 work he had no pain whatsoever. And it's the operation he
14 forgot.

15 The folks at DePuy, that is the -- the ideal. That's
16 what they're shooting for. They're not able to do it very
17 often, to put in a hip that you forget. It's a wonderful
18 thing. Ultima it's a marvelous thing.

19 Dr. Greer, again, he's done very well with his hip, very
20 little pain over the last three years. A man who exercises,
21 who rows, who chops wood, and he's able to do that with his
22 hip.

23 Captain Peterson again said it's better than I can say.

24 What activities were you able to do now that you weren't
25 before surgery?

1 On the ranch I can build fences, clear scrub, carry
2 animal feed and hay bales. On the bicycle, I can ride daily
3 and train strenuously. I can do all the walking, lifting
4 involved in normal life. All without pain.

5 That was for six years with his Pinnacle metal-on-metal
6 hip. It did what it was supposed to do, what it was designed
7 to do.

8 And doctor -- Mr. Klusmann, he had his left hip done, and
9 it felt so much better, relieved the pain, that he had his
10 right hip replaced with the same kind of a device.

11 Just months after having both hips replaced he's hiking
12 and canoeing.

13 In fact, they did receive relief of pain and the ability
14 to do their activities.

15 There are risks and benefits with everything in life.
16 And in the modern world there are choices in the kind of hip
17 surgery -- hip implants you can have. Each one of them have
18 different risks and different benefits. Not one of these
19 devices is perfect. We are not good enough to make a perfect
20 hip. I want to admit that right up front. If anyone thinks
21 that that's the standard, we have no chance here because we
22 can't build a perfect hip.

23 But each choice comes with differences. A real choice
24 means real differences. If you have a real choice, it implies
25 you get different benefits. A real choice means you also may

1 have different risks. And that's the truth of hips. A real
2 choice wouldn't be a choice between -- Well, today in America
3 you get to pick a black Chevy Malibu or a white Chevy Malibu.
4 That's not a real choice. The real choice involves
5 differences in benefits and differences in risks.

6 After a lot of work over, goodness, going back into at
7 least the 1930s and '40s, the materials that are available to
8 use in hip replacement surgery are basically three. There is
9 ceramic, there is metal, and there is plastic.

10 Now, over the years ivory was tried. There were even
11 some -- Teflon was tried by Dr. Charnley. It didn't work.

12 What else is tried? Diamond-coated surfaces on hips was
13 tried. All of this was an effort to make it do better. And
14 the story of hip surgery is a story of iterative progress.
15 You move, you move. You try to learn from the past and do
16 better. That's the story. We're not perfect yet.

17 And the risk and benefits are well-known to surgeons.
18 This is no surprise. The risk and benefits and the
19 differences have been talked about and debated for years and
20 years and years.

21 Here's an article that happens to set out all three in
22 one little slide. This I think was published by Dr. Ian Clark
23 back in 2008. And it talks about the difference risks.

24 With metal there's no surprise. The risk of a biological
25 reaction, tissue reaction, has been well-known as a

1 possibility with a metal-on-metal device decades ago. It's no
2 surprise to anyone that a metal-on-metal can cause a tissue
3 reaction.

4 And there are benefits and risks to all the different
5 devices. And they're just set out here in the scientific
6 literature for anyone paying attention to know about.

7 Now, from the very beginning it became obvious that the
8 enemy of hip replacement surgery was wear.

9 What do I mean by wear?

10 Well, any time you rub two surfaces together, they create
11 wear. And some of it is microscopic. The amount of wear
12 created by a metal-on-metal device is minuscule, but it
13 exists. The amount of wear created by a ceramic device is
14 still even more minuscule but it exists. Plastic actually
15 creates the most wear.

16 Why is it important?

17 The body doesn't like foreign stuff being put inside it.
18 It doesn't like it.

19 I don't know if any of you are old enough, have had
20 enough taste in movies -- do you remember the movie Inner
21 Space? I think it was Meg Ryan, Dennis Quaid and Martin
22 Short. The gist of it was they shrunk this little submarine
23 down to microscopic size, and they injected it into a person,
24 and the submarine is going along in the blood vessel, and it's
25 being attacked by the body defenses by cells, macrophages, by

1 eosinophils, different things the body sends after anything
2 that goes into it. The body attacks wear, doesn't like wear,
3 doesn't like anything for it, including sometimes an organ.
4 You get an organ transplant sometimes they're rejected because
5 the body doesn't like it. But all of these devices create
6 wear. There are genetic differences in humans. That's no
7 surprise. Humans are a funny bunch. We're all a bit
8 different. And genetic differences can cause you to have a
9 bad reaction to a relatively small amount of plastic. You can
10 have a bad reaction to a relatively small amount of metal, and
11 that's what they were talking about here, an immune reaction
12 to a relatively small amount -- a low and expected amount of
13 metal wear can cause an immune reaction. That's exactly what
14 happened to Mr. Klusmann, exactly. His device worked
15 beautifully. His body didn't like it at all.

16 What are the risks?

17 Well, they have all got their risks.

18 Ceramic never took off in the United States. It's
19 starting to become more popular. In Europe, France,
20 Germany -- all the European countries -- they love ceramic.
21 It's a product they think is great and have used it for
22 decades with a lot of success. But one of the major risks --
23 all of the ceramics, what happens when you drop a ceramic
24 piece, pod or good, it shatters. Well, these hips could
25 shatter in the body, and it's a disaster because it creates

1 shards of highly small ceramic that can utterly destroy any
2 new implant that's put in to replace it. It can destroy metal
3 because the ceramic is actually harder than the metal. It
4 chews up plastic. It's a rare risk, the shattering, but it's
5 a risk that happens, and it's terrible for the person that has
6 it. That's one of the reasons ceramic never took off in the
7 U.S. It can also squeak, which doesn't sound like a big deal,
8 but think about it if you've got a hip and people can hear you
9 walking across the room, you know, it's a thing -- it's not
10 something you want.

11 Plastic devices. Plastic devices are great. DePuy makes
12 some of the finest, the most effective plastic devices on the
13 planet. They are absolutely wonderful and if -- If Mr. Lanier
14 said I am going to criticize plastic, I'm not, because plastic
15 is a terrific surface, but it doesn't come without its own
16 risk. It creates thousands of particles with every step you
17 take. Over the course of a year you create hundreds of
18 millions of particles of plastic. And the plastic particles
19 that are created, they don't go away. You've seen the
20 pictures of the -- the Marine mammals with plastic in their
21 gills and things. It's because plastic doesn't degrade. And
22 the body stores it up.

23 So what you see here is tissue from a patient that had a
24 metal-on-plastic revision. On the left, it doesn't look so
25 bad. But if you put it under polarized light, that same

1 tissue, that lights up, and it stays there in the tissue. It
2 accumulates. It builds up.

3 Now, metal is not without its risks. It has benefits,
4 but it absolutely has the risk that in some patients metal
5 wear debris can cause a tissue reaction. That's been known
6 for decades. Doctors know it. The FDA knows it. All the
7 regulatory bodies around the world know and understand that
8 this is a known and expected risk.

9 So it's not a surprise that some patients will have that
10 happen.

11 What's the difference in the way the body reacts to metal
12 and plastic?

13 It does react differently. No surprise. Different
14 things mean different reactions. Metal particles can be
15 handled by the body and excreted, but the body doesn't do that
16 with plastic. And this has been known -- when was this
17 published? Over 20 years ago. About 20 years ago. Known and
18 understood.

19 I'd like to talk a little bit about the history of how we
20 got where we are in hip replacement. These are some of the
21 true geniuses behind the development of total hip replacement.
22 The one Mr. Lanier talked about is John Charnley. He may be
23 the genius among geniuses because he came up with a wonderful
24 device, metal-on-plastic device, that has been great for
25 decades. In fact, I've got one.

1 This is the old Charnley device explanted from a patient
2 and studied by Dr. Pat Campbell, who you will get to hear
3 from.

4 There's the femoral with the head put into the hip by the
5 femur. And this part, how do you get it to stick in the
6 person? How do you get this acetabular to stick?

7 A lot of different ways are tried. Dr. Charnley chose
8 glue, cement, a polymethyl methacrylate. It's a dental
9 cement. It worked. It would stay in place. And this is the
10 way you would articulate.

11 The other gentlemen here all did different things, but
12 the reason they did it -- this is back in the -- going to the
13 '40s and '50s -- their patients would come to them, tremendous
14 pain, tremendous disability, unable to sleep and to move and
15 live, and they -- they refused to say, I'm sorry, I can't help
16 you. They refused to take no for an answer. And so they
17 tried things.

18 Dr. Charnley tried -- Teflon was one of his first. It
19 didn't work at all. But it's not because he wasn't trying.
20 He absolutely was trying. He refused to say to patients the
21 one thing I can do for you if you don't want to go sit on a
22 porch like Mr. Powell said, I can do something called a
23 Girdlestone procedure. What's that? The Girdlestone takes
24 out the entire hip joint. It's gone, the pain is gone because
25 your arthritis isn't there anymore. But your hip is gone,

1 too, and moving around becomes extraordinarily difficult. It
2 is a gruesome operation but many people chose it because they
3 couldn't stand the pain anymore.

4 Here are some of the very first devices. Look at the
5 screws. Very, very crude.

6 What is really strange is that these x-rays, they're
7 taken two years after implant. Those things actually worked.

8 You're going to hear about a device called the
9 McKee-Farrar. It's one of the first metal devices. I might
10 have one here.

11 I don't have it, but I'll bring one. It worked great.
12 McKee was one of the -- the contemporaries of Charnley. They
13 actually talked. They worked together.

14 And this was a metal-on-metal device that worked in
15 patients. And it -- it did well on some patients and it did
16 poorly in others. It wasn't perfect, but it worked. And for
17 decades it provided pain relief to many, many people.

18 We've talked about the Charnley, and I talked about the
19 cement. That's how he got it to stick.

20 McKee actually used cement to make -- make his stick in
21 the body, too.

22 Ring is another device that tried a different method.

23 See that big screw at the top?

24 They would actually screw that up into the pelvis to try
25 and make the device stick. You've got to make it stay in

1 place or nothing works. Nothing works.

2 Tried all kinds of things.

3 One of the things DePuy is most proud of is it found a
4 better way to make the device stick, to make it stay in the
5 hip.

6 Back in 1977 DePuy came up with what's called POROCOAT.
7 And POROCOAT is putting beads of metal, microscopic beads now,
8 of metal that encourage your natural bone to grow into the
9 device. It's a whole lot better than cement. It's a much
10 better bond. And DePuy figured this out decades ago. And
11 it's been a fantastic innovation and achievement for millions
12 of people.

13 But that bone growing in now saves you from having
14 cement. You don't have to use screws. And it's one of the
15 things that goes with the Pinnacle device. It is a fantastic
16 cup and has been for decades.

17 Here's just a -- so many ways, so many choices were
18 offered to patients over the course of the years. Many of
19 them were fraught with risk. But they're trying to solve a
20 serious problem.

21 And what has happened is that innovation has made efforts
22 get better. We're better in 2015 than we were in 2010, 2005
23 we're better. And we hope that we're not done yet. We hope
24 that in 2020 it'll be better and that your children will have
25 something even more fantastic. Maybe somebody will invent the

1 new device that is the perfect device. But we're just not
2 there yet.

3 And innovation continuing doesn't make what came before
4 defective. It -- it shouldn't come as a surprise to anyone
5 that a device that was designed and -- and -- and built and --
6 and created in the 1990s and 1980s is no longer on the market
7 in 2015. That shouldn't surprise anyone, because innovation
8 is so important to American medicine.

9 None of these devices, the McKee-Farrar, the -- the first
10 ceramic device, the Autophor, nobody uses Charnley anymore.
11 They were not defective. Innovation has simply gone beyond
12 that.

13 It's like, I use an iPod, I don't use a gramophone. I
14 use a small cell phone, I don't use the big blocky thing.
15 Don't use VCRs anymore, probably none of you do either.

16 They're not defective because progress has gone beyond.
17 And they're accusing us of creating a defective product when
18 in fact innovation has simply moved on.

19 Turned out, and this was a surprise to everyone,
20 including Dr. Charnley, there was a hidden problem with the
21 Charnley device that he didn't know about, nobody knew about.
22 The Charnley device worked so well that it really pushed a lot
23 of the other devices, including metal-on-metal, off of the
24 market. It really did well. But it had a hidden problem.

25 What was it?

1 The plastic in the device caused a tissue reaction in the
2 bone and caused the bone to melt away. Took a while. It
3 might take five, six, seven, ten, 15 years, but eventually
4 what happens is these plastic particles are released, the body
5 responds with -- it's like a little Pac Man, macrophages
6 they're called. And the macrophages attacks the plastic. And
7 when it does the macrophages releases chemicals. And the
8 chemicals are chemokines and different cause the bone to
9 resorb, the bone to melt away. And when that happens the
10 device can't stay in place. The bone melting away is called
11 osteolysis. And you're going hear a lot about osteolysis.

12 Osteolysis is bone melting away. But the Charnley device
13 wasn't defective. It had a risk. And using the device
14 doesn't make you bad, it means you've chosen to accept a risk
15 to -- to relief the pain but the risk is osteolysis. Charnley
16 was never defective.

17 Now, what happens?

18 This is an example from one of the surgeons you're going
19 to hear testify today, a surgeon from Dallas. The patient
20 here had severe osteolysis. And look, look where that hip is.

21 Not supposed to be there. It's about three inches beyond
22 where it ought to be. It's way inside the pelvis now.

23 That's because the bone melted away. Bone's gone. And
24 bone's gone and the device is shoved up into the pelvis and
25 all of a sudden your leg is three inches shorter. That's what

1 happened.

2 The surgeon here performed an heroic operation. And look
3 at this contraption that he had to develop in order to make it
4 work. And the great thing is she's fine. It worked.

5 So while osteolysis can cause bone loss, it's a serious
6 problem, it's a serious risk, but it doesn't make the plastic
7 defective. It's just a risk that you must accept if you want
8 that device.

9 This is from Pat Campbell's lab. And it looks kind of
10 like a scoop of vanilla ice cream. That's melted-away bone
11 that's called by osteolysis.

12 And osteolysis is -- is a silent disease. It doesn't hurt
13 while you're bone is melting away, but if you let it go too
14 long you have the reaction that you saw that required the
15 contraption to fix it.

16 Now, plastic just didn't work as well for younger
17 patients. But nobody knew that. No -- nobody knew that
18 when -- when they were starting out. Now, Charnley didn't
19 know it very much, because he was very strict on who he would
20 give his device to. He would implant very elderly people,
21 primarily, and people who wouldn't want to put a lot of stress
22 on it. He's from England. And primarily he would put it on
23 people who their activity was going back and forth to the
24 kitchen to get their pot of tea and walk back into the living
25 room. He didn't want a lot of activity on his device.

1 And younger patients provided a very challenging
2 population. Plastic had trouble with younger patients.

3 Now, here's a study that shows that the plastic devices
4 were doing great at ten years. A 90 percent survival rate at
5 ten years. They're doing great.

6 But look what happened at 14 years.

7 14 years it's down to 56.3 percent. And that's because
8 of the osteolysis, the buildup of the plastic and the erosion
9 of the bone. It doesn't make the plastic defective, it's
10 simply a known and understood risk.

11 They found that around the world. In -- in Sweden they
12 found the same thing. In younger patients the plastic didn't
13 last as well as older patients, and the revision rate was 30
14 percent at 11 years.

15 So the orthopedic community and surgeons, they didn't
16 abandon plastic, they didn't reject plastic, they didn't say
17 it was defective, they said give us something better. And the
18 orthopedic community demanded of regulators, of scientists, of
19 medical companies like DePuy, give us something better.

20 So they carefully considered metal-on-metal. Here's the
21 National Institute of Health for the United States, back in
22 1982. And they held a conference looking at how do we make
23 this better. We've got a problem with plastic, what do we do?

24 They looked at metal and they -- they recognized that
25 small metal particles are a risk, you have allergic reactions

1 to the alloys. But they didn't stop it. They said move
2 forward. Move forward and let's see if we can find something
3 better.

4 In 1995 there was one of the largest meetings of
5 scientists, surgeons, medical professionals, and companies to
6 pig out what do we do, should we proceed with metal-on-metal?

7 It was not something that was undertaken in the back
8 rooms of -- of some company. This was debated among
9 scientists for a long time before the DePuy device was ever
10 launched. They debated. And -- and there was back and forth.

11 You're going to hear that there were scientists in favor
12 of metal, scientists against metal. And he ever is out in the
13 open. Eyes are wide open about risks and the benefit of metal
14 because they studied it, debated, talked about, and published
15 about it.

16 The risks of metal have been published about for decades.
17 Just like the risk of plastic had been published about for
18 decades, going back to the '70s, the '80s, the '90s, 2000.
19 The potential risk of the metal-on-metal device had been
20 published.

21 Anyone paying attention knows about that risk.

22 We're -- we're going to talk a lot about scientific
23 literature. I'm sure Mr. Lanier and -- and Mr. Cannon will
24 have scientific articles they'd like to show you. We will
25 certainly do that. But where do surgeons and medical

1 professionals get their information?

2 Some of you I know are well-aware of the scientific
3 literature because you use it in the course of -- of your
4 work, but these are journals that are called peer-reviewed
5 journals. And this is where scientists and doctors get their
6 information. They don't get it from the advertisements that
7 Mr. Lanier spent so much time talking about.

8 In fact, these surgeons, the ones that are -- are going
9 to testify in this case will tell you we didn't rely on any
10 advertisements, and never would, that's ridiculous.

11 What's the word he says I like?

12 "Outrageous." It's outrageous to think that doctors
13 would rely on advertisements to choose what devices to put in
14 their patients. They don't. They didn't. Will not. They
15 rely on scientific evidence.

16 And the other thing about those ads: He talked about
17 patients going to their doctors and asking for devices. Well,
18 this case is about these five plaintiffs. Not one of these
19 five plaintiffs read those advertisements that he spent so
20 much time on, not one of them relied upon them, not one of
21 them used them, not one of them took them to their doctor.
22 Why is it spending your time on something that has nothing to
23 do with this case? Nothing. All these advertisements have
24 nothing to do with this case.

25 But they might make you mad. And do you make your best

1 decisions when you're mad?

2 You don't.

3 And someone trying to make you mad is not asking you to
4 make your best decision.

5 Why cobalt chromium?

6 It's been used for 80 years.

7 Cobalt chrome has been used for 80 years in human beings.
8 Because it works. It's strong. It reacts pretty well to the
9 body. The body doesn't hate it. It's not a poison, like
10 Mr. Lanier tells you. You will hear evidence from medical
11 doctors, from scientists, who will say it's not a poison, good
12 grief. The body needs cobalt chromium. In fact, if you take
13 your vitamins, and I'm over 60 so I take my Centrum Silver,
14 and it's got chromium in it, cobalt in it. It's something the
15 body knows how to handle.

16 It's real important to remember that when you have
17 choices you have different risks. And the risks of metal were
18 well-known, understood in the medical community for decades.
19 You just have to be paying attention. And these doctors were.

20 Now, he was talking about how the Charnley was so much
21 better than -- than the metal-on-metal devices.

22 Turns out they're just different. There were studies
23 comparing Charnley, which is the plastic one, to the McKee,
24 which is the metal one, going way back. Now, these devices
25 were put in a long time ago.

1 And here's what they found out:

2 The McKee is the -- the orange line, and the Charnley
3 device is doing better. Looks like it's doing better for
4 first ten years it's certainly better. First 15 years it's
5 better.

6 If you go out to 20 years it turns out the opposite. The
7 McKee, the metal is actually outperforming the plastic.

8 That doesn't mean it's better. That doesn't mean plastic
9 is defective at 20 years. It just means the choices are
10 different. And to have a real choice replies -- implies real
11 differences. That's all.

12 Now, somehow this got lost in Mr. Lanier's story. And he
13 tells a great story. I love to hear him tell stories. But
14 stories aren't always true. Fiction is written and -- by --
15 by many authors and it's very popular.

16 So he's got a storybook that he wants to tell you about
17 but he missed a pretty big part of the picture. Because DePuy
18 didn't just come out and start making its own device, after
19 those first generation metal-on-metal devices going way back
20 into the '50s, the folks in Europe went to metal way before
21 DePuy did. And it did great.

22 In the '80s and '90s there were thousands of different
23 surgeons using metal-on-metal in Europe, Switzerland, Germany,
24 France. And they're having great results.

25 We talked earlier that the -- the Europeans loved ceramic

1 much better than -- than the U.S. did. It's just a different
2 choice. But they used it long before we did. They also used
3 metal long before we did. And they had good results. And
4 they published it in the literature. And DePuy paid
5 attention. They listened to this.

6 Now, when you're talking about how do you know whether a
7 device works in the human body, you can do petri dish studies.
8 You can do clinical studies. More importantly, you can pay
9 attention to what real people are doing with real devices
10 implanted in them. And around Europe thousands of patients
11 had these devices and it was published in the literature, and
12 the results were good.

13 Dr. Wagner and his son, also Dr. Wagner, used many, many,
14 metal-on-metal devices, published about 'em, and had great
15 results.

16 The same is true throughout.

17 In fact, the results were so good that some of the
18 longest lasting results published in the literature were
19 metal-on-metal, really good results.

20 And DePuy paid attention to that. And I know Mr. Lanier
21 talked about Graham Isaac and his -- his paper back from '95,
22 but they're paying attention can these devices work, do they
23 work. And, in fact, they do.

24 So DePuy offered surgeons choices. What they did is take
25 that great cup we talked about, that POROCOATED cup, they

1 allowed surgeons to choose to put in that cup. You can put in
2 plastic. You can put in ceramic. Or you can put in metal.
3 In one cup. It's a remarkable achievement. But that's what
4 DePuy offered with the Pinnacle device.

5 It -- it's -- in fact, DePuy has always had more users of
6 plastic with its device than it has with metal.

7 DePuy has innovated plastic and has been at the forefront
8 of trying to make a better plastic from the very beginning.
9 DePuy is absolutely not against plastic. We make some of the
10 best in the world.

11 In fact, DePuy invented the first cross-linked plastic --
12 intentionally cross-linked plastic that the FDA cleared in
13 1998 in this country. So to say we're against it is utterly
14 false.

15 But, this is from the British FDA. It's called the MHRA.
16 And they said, look, wait a minute, people, surgeons, we don't
17 know what these new plastics are going to do. And the new
18 plastics are different than the old Charnley plastic for a lot
19 of reason. They can make it different in a lot of ways.

20 But primarily what they do is irradiate it. They
21 shoot -- they put radiation into the plastic. And it causes
22 the molecules in the plastic to get all cross-linked together.
23 That -- that has really good things that come with it. What
24 it does is it makes it much harder. It becomes a much harder
25 surface but it also becomes more brittle. When you make

1 things harder you make it more brittle. It's a trade-off.

2 So you make it harder. You get less wear. That's great.
3 But it also can fracture. So you add that risk to the
4 equation. It's that same what risk am I will to take. It's
5 the bargain you accept when -- when you accept the product.

6 So DePuy -- the -- the Marathon was actually irradiated
7 with five mega-rads of radiation. Turned out to be a great
8 plastic.

9 But, you know what, DePuy didn't stop there. Marathon
10 wasn't where they dropped. They've invented another --
11 another plastic called ALTRX that they think is even better
12 than Marathon. The Marathon is still good. It's not
13 defective. ALTRX has more radiation. And now they're going -
14 they -- the research is going beyond that. It haven't
15 stopped. DePuy is trying to make the best plastic on the
16 planet. And they're not done.

17 Plastic took the same kind of course metal did. There
18 are some metal-on-metal devices that haven't worked well. And
19 the ASR is one of them. And Mr. Lanier talked about that.
20 But there are many plastic devices that didn't work well. It
21 didn't mean that plastic was defective. It just meant that
22 the idea behind that plastic device wasn't as good as others.

23 Carbon-reinforced plastic wasn't the best plastic.

24 Something called Hylamer, which is pressure-intensed
25 plastic, that didn't work well either.

1 Many different companies tried different things to make
2 the plastic better.

3 DePuy is not out there on its own. There are -- there
4 are really good medical device companies in this country that
5 have come up with different ways to make plastic, and many of
6 the plastics are really good. So to say we're condemning
7 plastic is -- is just not so.

8 But we talked about the risks.

9 The more radiation you put in this plastic to make it
10 harder the more brittle it becomes and a risk you have is
11 fracture. It can break. But you accept it. It doesn't make
12 it defective. It's just a risk.

13 Now, DePuy -- Mike Powell and I, I suppose could go to
14 his garage here in Dallas, and try to create some sort of
15 medical device. It would be a terrible idea for us to do
16 that. DePuy acted responsibly in its innovation of metal.
17 And it took a long time. It started way back before it
18 released it. You go back to 1992 and they're working,
19 designing, innovating, inventing, testing metal before it was
20 ever released to the public.

21 And of course before it can be released to the public if
22 Mike and I want to invent some kind of device we can't just
23 sell it to people. The FDA in this country has to either
24 clear or approve anything that you can sell. And, of course,
25 that happened.

1 This is a busy slide that gives you an idea of the dozens
2 and dozens of medical tests DePuy employed on the
3 metal-on-metal device for years before it ever sold the
4 device.

5 This is that simulator that Mr. Lanier talked about.
6 Yes, indeed, it does go back and forth. Yes indeed, it does
7 do that. It is a best way to determine how a device it wears.

8 We didn't have a test where the hip simulator had us
9 skipping on one foot and singing a song while we're doing it.
10 That's ridiculous. We didn't do that. We ran the test that
11 the International Standards Organization said was the right
12 test to use on hips. And we did it for a long time.

13 Now, you remember the Metasul device that was doing so
14 well in Europe? It seemed to DePuy that, well, how do we go
15 head to head? How do we compare (sic) against a device that's
16 working great in people. The Metasul device was working great
17 in humans. So they decided to put the Metasul in their
18 simulator head to head with the Ultima device which is another
19 metal-on-metal device that they were working on at the time,
20 and they compared the wear rates. It turned out our metal was
21 wearing less than the Metasul. It's just a logical
22 comparison, and that's the kind of testing they did.

23 Two billion cycles. What does that mean? Most of us if
24 we're active will walk between one and two million cycles a
25 year. So two billion cycles we're looking at over a thousand

1 years of human beings walking. That's the kind of testing --
2 And this took a long time. In order to do this, you've got
3 tests that last for months.

4 One test will last for months before you finish it. But,
5 you know, it's hard to hear the things that the plaintiffs say
6 about DePuy because these are good people doing their very
7 best to make good products, and they did a tremendous amount
8 of work to do that.

9 Now, the FDA was paying attention. The FDA in this
10 country cleared the Pinnacle metal-on-metal, the Ultamet
11 device, and it also cleared 190 metal-on-metal devices from
12 various manufacturers.

13 The FDA was paying attention.

14 Now, we know that -- You remember that meeting back in
15 1995 with UCLA with the hundred scientists? Two of those
16 scientists were FDA scientists, and they were there to hear
17 the debate about the good and bad of metal. They did more
18 than just listen. They published in the peer-reviewed
19 literature, Dr. Kathy Merritt and Dr. Stan Brown were
20 scientists with the FDA who talked about the risk of metal and
21 published on the risk of metal in 1996 including a discussion
22 of the very hypersensitivity reaction that Mr. Klusmann
23 suffered. This was well-known and well understood by the FDA
24 before they cleared these devices to be used.

25 And this is just kind of a timeline of the different --

1 the different tests that were done, the different entries that
2 were made to the FDA. And, in fact, there were clinical
3 studies done. The FDA approves a clinical study of the Ultima
4 hip. The FDA approved a study of the one-piece hip. So there
5 were clinical studies being done on real patients with real
6 metal-on-metal devices, studies approved by the FDA.

7 Here's the actual approval letter. I'm sorry. Here's
8 the actual clearance letter from the FDA from October of 2000.

9 Now, the FDA didn't have just information from DePuy.
10 DePuy was required to provide whatever information the FDA
11 wanted about its devices, but they also had -- had information
12 from all the different manufacturers who also made medical
13 devices. The FDA had an incredible amount of information
14 available to it and had improved the devices.

15 You know, what -- what's this case about? It's a product
16 liability case that requires them to prove our product was
17 defective. Has the FDA ever said that the Pinnacle
18 metal-on-metal device is defective? The answer is no. To
19 this day they have never said such a thing.

20 Now, as of 2012, the FDA had cleared 190 different
21 submissions for metal-on-metal devices in the United States
22 alone. And that's from their web site in 2015.

23 Around the world the equivalents of the FDA have
24 approved, cleared, or permitted the use of metal-on-metal
25 devices, the Pinnacle Ultamet, in 51 countries. They have

1 never -- No FDA has ever said your device is defective, you
2 have to re-call it. Never. 51 countries around the world.

3 Now, I'm not saying that the FDA equivalent in Egypt is
4 anything as good as the FDA in this country, but the FDA
5 equivalent in England, in France, in Germany, in Norway, in
6 Sweden, are all very sophisticated. All very sophisticated.

7 Here's what the FDA is saying on their web site.

8 "Overall, metal-on-metal hip implants have been shown to
9 provide high implant survivorship (no need to remove the
10 implant and put another in its place) in certain patient
11 populations."

12 That's a long, long way from saying a device is
13 defective. They have not said that.

14 The FDA even talks about the risk-benefit ratio that
15 we've talked about, and that's going to be so important in our
16 analysis.

17 For many patients, currently available information
18 supports a favorable risk-benefit ratio. That's the FDA as of
19 2015.

20 And, in fact, metal-on-metal has had good results. It
21 hasn't had always good results. And some metal-on-metal
22 devices haven't had good results at all. You heard about
23 those.

24 What you didn't hear about are the devices that have had
25 good results in different countries around the world.

1 We know that there is a risk of a tissue reaction. We
2 know that. Every person who is paying attention -- scientist,
3 surgeon, medical person -- knows that metal-on-metal can cause
4 a tissue reaction.

5 How often does it happen? There is studies showing that
6 from about 2013 the Dr. Wiley study showed in about 14,000
7 hips that the incidence of that reaction was .06 percent. The
8 study in Japan showing about the same number of hips, about
9 13,500, they found the ratio of metal reactions was about .5
10 percent with one kind of device and 1.2 percent with another
11 kind of device.

12 So we've talked about this before, revisions happen, but
13 you need to put in perspective how often is the revision due
14 to a problem with metal. In 2000 -- I'm sorry. I don't
15 remember the date of this article, but it's relatively recent.
16 This was the pie chart showing the different reasons for
17 revision. Metallosis was one of the reasons absolutely, but
18 if you put it in perspective, osteolysis, the risk for
19 revision to plastic was five times as high. Now, to be fair
20 you have to understand that there are more plastic devices
21 than metal devices. So the percentages have to be viewed --
22 Anytime you look at statistics, you've got to look hard at
23 statistics, right? Because statistics can be made to look
24 different ways by different people. So look hard at the
25 statistics. We'll try to be as -- as clear about that as we

1 can.

2 One of the things that -- that is important when we're
3 looking at the statistics of survivorship -- particularly the
4 survivorship of plastic -- is that there are lots and lots of
5 metal-on-plastic patients walking around with metallosis.

6 What they have found is there's a high percentage of
7 patients that are not revised but in fact have osteolysis.
8 Now, how long is it going to be before they are in fact
9 revised. How long is it going to be before the statistics
10 about the success of plastic look different?

11 Here these are patients -- 40 percent of these patients
12 who are unrevised have osteolysis. Here, it's 15 percent of
13 the stem part have osteolysis on the stem, and another 17
14 percent of the surviving have acetabular osteolysis. So you
15 have to pay attention to -- to statistics about survival when
16 you're looking at metal-on-plastic because there are many of
17 those devices that have osteolysis and yet are still in place.

18 The Pinnacle Ulamet has performed extraordinarily well.
19 Of all metal-on-metal devices, it has performed beautifully.
20 What we know is if you look at the different registries -- In
21 Australia, you're going to find that the Pinnacle Ulamet not
22 only is best in class, it's number one and number two. It's
23 rated number 1 with one stem and second best with a different
24 stem. The very best in class. And the second best in class.

25 In the Nordic registry -- That's a registry with Sweden,

1 Finland, Norway, Denmark -- I'm missing one. They found when
2 you look at the numbers the metal does just as well as the
3 plastic.

4 The U.S., I believe that's the Medicare database, they
5 found that metal and plastic performed the same -- I'm sorry.
6 This is actually the Health East registry because it's looking
7 particularly at the Pinnacle which performed just as well as
8 the plastic.

9 And in the UK, the registry that Mr. Lanier loved so much
10 metal -- Pinnacle Ultamet is also best in class.

11 How do we know?

12 Their expert, Dr. Al Burstein, who actually was present
13 at the 1982 National Institute of Health meeting that looked
14 at metal. He was there.

15 "Q. Is it accurate to say that the Ultamet outperforms
16 other metal-on-metal devices in the UK registry?"

17 Dr. Burstein: "It has better survivorship, yes."

18 So to say the Pinnacle is defective is wrong in so many
19 ways.

20 How would you evaluate a hip if you had one put in?

21 How would you do that?

22 The best way is how does it feel, how does it work?

23 Well, there are studies about that. The Harris Hip Score
24 evaluates how well the hip does. The Oxford hip score also
25 does. Our device has been studied. How well does it do?

1 It does great. You take the patients before and after.
2 Before hip surgery the -- they're doing very poorly on the
3 Harris Hip Score. After, the results are excellent. Across
4 the board poor to excellent. That's the test of whether a
5 product works. That's the test of whether a product is not
6 defective. And here is one of these studies that we're
7 looking at. We've talked about how these become the knowledge
8 of doctors. That's where doctors go to get their information.
9 They don't -- they don't go to an advertisement. Doctors
10 study. They look at the scientific research.
11 This is just another study showing how well the -- the cup
12 performs. This is just the cup part. It performs
13 beautifully, virtually a hundred percent survivorship at ten
14 years. 97.9 if you include reoperation for any reason.
15 The Pinnacle cup is an incredible cup, and the company is
16 justly proud of it. How do surgeries choose? How do they
17 pick? We know that they are highly trained. Hopefully, I
18 won't become too annoying with this, but I'm so proud of my
19 daughter, every chance I get I talk about her. She's in her
20 first year of residency at the University of Chicago. I about
21 beam every time I talk about her. But surgeons just don't go
22 to a little bit of school. It's four years of medical school.
23 To become an orthopedic surgeon, it's five years of residency
24 and another fellowship so they learn how to do specialized
25 things. They get board certified. They continue their

1 training throughout their career. And the essence of the
2 practice of medicine is choosing the right device for your
3 patient because what we know for sure is surgeons are
4 individuals. They're not all the same.
5 Even something as simple as are you a left-handed surgeon, are
6 you a right handed surgeon, it matters. And different devices
7 work differently in different surgeon's hands. Some of them
8 love metal, some of them love plastic, now -- not very many,
9 but now in the U.S. you can get ceramic. Used to be not so
10 long ago if you wanted ceramic as an American you had to go
11 over to Europe to get it. Now it's available as a choice here
12 in this country, too, and different surgeons love it, and some
13 surgeons hate it. Choices.

14 And like I said, people are a funny bunch. We are all
15 different. We are all so different. Which is a good thing.
16 It's a beautiful thing. But different people have different
17 needs. It wasn't very long ago when surgeons had to make the
18 patient fit the hip device. Today because of innovation by
19 companies like DePuy, you can make the device fit the patient.
20 Here, again, we've talked about Pinnacle offering these
21 choices. The great shell, you can put in ceramic, metal or
22 plastic. And they're all good options. They all have their
23 risks, all have their benefits. Not one of them are
24 defective.

25 How do surgeons choose? You're going to hear from

1 Dr. Emerson. He will testify in this trial. He wrote in 2005
2 in the peer-reviewed literature how he did choose. Talking
3 about metal "We do, however, weigh the potential unknown
4 effects of metal ions against the potential benefit of
5 improved wear characteristics and lower dislocation rates
6 during our pre-operative discussions with our patients and as
7 a standard part of the operative consent." That's how it's
8 done. Surgeons look at the literature, know the risk, weigh
9 the risk and talk about it with their patients. That's the
10 right way to indict.

11 These plaintiffs are all different and Mr. Cannon asked
12 me to do this, Mr. Lanier asked me to do this. I will tell
13 you what the evidence will show on why they were revised.
14 They're all different people, and they're all highly
15 accomplished people, very successful at what they do, but
16 they're all different. Remember that, because you're going to
17 be asked to evaluate each of them individually.

18 Now, we talked about this. This is just a reminder, and
19 I'll talk about it in detail, but Mrs. Aoki revised because
20 her hip was unstable. Mr. Christopher because of the
21 bleeding. Dr. Greer, his autoimmune disease, Captain Peterson
22 because of the pre-existing cyst that came back. And
23 Mr. Klusmann, the hypersensitivity.

24 Now, how do we know that they're all different?
25 Let's take a look at how the devices performed, because we --

1 Dr. Campbell evaluated and tested the amount of wear that came
2 from these devices.

3 Mrs. Aoki, who had her device for the lowest amount of
4 time, had by far the highest amount of wear. How is that
5 possible?

6 We're going to tell you.

7 But the others, for seven years, over six years, had very
8 low wear. A minuscule amount of wear, which means the device
9 is minding its own business doing what it's supposed to do
10 inside their bodies and the revision happened for another
11 reason.

12 Okay. How do we know Mrs. Aoki was unstable?

13 Because she told us.

14 Her medical records are filled with references to the
15 instability of her hip. She always felt a bit wobbly in PT,
16 but was told that just increasing her muscle strength would
17 help that.

18 That's right. The muscles were lax and if you could
19 somehow make them tenser and tighter it would -- it would get
20 the instability out.

21 The hip always had a feeling of instability to it. And
22 it's gotten worse. And then they started to feel she had a
23 clunk. Well, you're not supposed to feel a clunk in your hip.
24 That's not normal. That's not right. And it's the
25 instability, the tissues were lax, causing the head to move

1 out and clunk back into the hip.

2 And then she got squeaking.

3 Well, ceramic devices can have squeaking.

4 Metal devices, unless something is not going right don't
5 squeak.

6 She had squeaking reported multiple times.

7 And then when she was revised Dr. Pearce did a revision,
8 inside the revision inside her hip he was able to find
9 pistoning.

10 Well, pistoning is, again, caused by laxness, moving back
11 and forth, in and out of the hip.

12 When he fixed her, when he revised her, and he did -- and
13 we'll talk about how he fixed it. He rigged the instability.
14 After he put the trial in we had better stability, no
15 pistoning, and very good stability.

16 Once again, very good stability and no pistoning. He
17 emphasized that in his operative report because that's how he
18 fixed her.

19 And this is the result of that pistoning. This is called
20 edge wear. This is a photo of her actual explanted device
21 taken by Dr. Campbell.

22 And this is an edge wear map. The green is low wear.
23 And the red is high wear.

24 And so what happens is as you're moving the head out
25 you're sliding across the edge. When you do that with the

1 pistoning, the clunking that she had, you're wearing on the
2 edge. That's why she had high wear and the others had low
3 wear.

4 And her -- her blood ion levels were high too. Now
5 surprise. She had high wear. She had high ion levels. And
6 remember, that's how the body is reacting to the metal wear
7 debris. It's handling it. It's treating it. It's sending it
8 out through the blood.

9 Stable joint, it's well within the socket.

10 And subluxation, unstable joint, it's out to the edge.
11 It's really that simple.

12 But we warned -- DePuy has warned about subluxation and
13 dislocation from the beginning. It can happen. If you don't
14 get the joint tight enough, if the joint is lax you can have
15 subluxation, you can have dislocation. And we told the
16 doctors that. But they knew it anyway.

17 How did -- how did Dr. Pearce fix her?

18 Okay. This is kind of busy but it's actually pretty
19 cool. This is her original surgery. And she had this much
20 length between her -- her hip bone and the start of her femur.
21 64 millimeters.

22 He lengthened it to 70 millimeters when he was doing the
23 surgery. It's not a lot but it was enough, four and a half
24 millimeters of extension and length caused her tissues to be
25 tight enough that she's not unstable anymore. That fixed it.

1 Okay. What we know is the reason for her revision was
2 instability and had nothing to do with whether her device was
3 made out of metal, wood, plastic, ceramic, or anything else.
4 It wasn't a defect that caused her revision.

5 Now, Mr. Christopher, he has the blood in his joint,
6 hemarthrosis.

7 How do we know?

8 Well, let's talk about him from the beginning.

9 Well, first, he was originally diagnosed with avascular
10 necrosis, by -- by his doctor. Reasonable diagnosis, turned
11 out that wasn't correct. And they only found that out on
12 pathology. He had osteoarthritis like three of the other
13 plaintiffs here. And he had restrictions in all of his
14 activities of daily living. He needed a hip.

15 So he got the hip. And he did great. Absolutely great.
16 Surgeon doesn't even want to see him back until three years
17 later. He's done well and regained good function in his hip.

18 But about five and a half years later he comes back to
19 see his doctor. And here's -- here's what original they found
20 "After his primary hip replacement" he had no pain whatsoever.

21 This is great. This is the hip that he forgot. This is
22 the Pinnacle metal-on-metal hip that they're saying is
23 defective. It's the hip he forgot.

24 But he comes back in, in June of 2015. And he's had his
25 hip replaced in 2006. Then great.

1 Then he had right groin pain that started two, three
2 weeks ago. A sudden onset of pain.

3 That's important. You've got to remember that. He does
4 do a lot of heavy lifting. That's what his doctor reports.

5 Okay. That's important too.

6 He writes, the patient may be having a metal-on-metal
7 reaction. He's concerned that that's a possibility. And he
8 recommends the patient get a chromium and cobalt level and a
9 MARs scan of the hip. He -- at this point he was already
10 thinking, well, it'll probably lead to a revision of the
11 components, because, as -- as Dr. Cannon -- or Mr. Cannon
12 said, Dr. Kearns was someone who he was never in favor of
13 metal-on-metal and he was somewhat spring-loaded to take it
14 out.

15 But let's see. The test he -- he decided to order, these
16 metal ion levels, they're -- they're almost nothing in
17 Mr. Christopher.

18 For the cobalt level, it's non-detect-- can't find it.

19 The chromium is well, well within normal limits.

20 That tells you the device is doing fine. It's operating
21 the way it's supposed to operate.

22 Now, when he did -- he did the revision surgery because
23 of the pain in the hip. What'd he find?

24 He says he saw a metal-on-metal reaction encountered with
25 fluid and synovial hypertrophy. But then he describes the

1 fluid. The fluid he describes as yellowish-greenish fluid.

2 Now, Dr. Emerson will tell you that's what you'd expect
3 from a hip with hema -- hemarthrosis. That's what you would
4 expect from a hip with a bruise in the joint, blood on the
5 joint. That's what you would not expect from a hip with a
6 metal-on-metal reaction. They look different.

7 And the pathology confirmed it.

8 In the pathology they're predominately macrophages,
9 remember those little Pac Men that eat up the plastic? They
10 also eat up old blood. Macrophages with brown pigment in it.

11 And the lymphocytic reaction, which is one of the things
12 you look for in a metal-on-metal reaction, that wasn't present
13 in the pathology.

14 Pathologists, you're going to hear from Dr. Scott Nelson
15 from UCLA. He's going to talk to you about Mr. Christopher's
16 tissue and how it looked good and how he found golden-colored
17 pigment in macrophages in his -- in his tissue and that the
18 best explanation for that is that they're old blood.

19 So he's got pain. He's got swelling in his joint. And
20 the pain is most likely caused by pressure from the bleeding
21 of his hemarthrosis. It was not caused by a metal reaction.

22 So, again, Mr. Christopher was revised but not because of
23 any defect in his Ultamet hip.

24 Dr. Greer is our next plaintiff. Dr. Greer suffered from
25 an ongoing autoimmune for much of his life.

1 THE COURT: You've got five minutes.

2 MR. SARVER: Thank you, Your Honor. Appreciate it.

3 He was diagnosed originally with polymyalgia rheumatica
4 that had these kind of symptoms.

5 He was eventually given a -- an Ultamet hip. And he
6 started having some symptoms that caused him to go to an
7 infectious disease specialist who actually nailed the diagnose
8 early on. He said consider the possibility this is an
9 autoimmune process related to his polymyalgia or that he has
10 developed a more aggressive autoimmune disorder with joint
11 involvement. He had a sarcoid in his hip that caused pain.

12 And the pathologist will tell you -- this doesn't mean
13 anything to me either, I know -- I know it doesn't mean
14 anything to you, but this is classic for a sarcoid, and that
15 means pain. You've got inflammation in the hip that led to
16 his pain, had nothing whatsoever to do with metal.

17 Now, Dr. Greer continues to have some thigh pain. And
18 the reason for his thigh pain is that the stem of his hip is
19 actually put in a little off-kilter and it's impinging on the
20 bone at the bottom of his -- of his -- the stem. It created a
21 notch in his femoral cortex, that's continuing pain. And the
22 stem is left in place.

23 So Dr. Greer is going to have to decide on his own choice
24 do you want to have the stem replaced or not. That will fix
25 the pain.

1 Captain Peterson, the preexisting cyst:

2 We know that the reason he had THA in the first place
3 was because he's a cyst developer. Incredible athlete. But
4 he needed the hip because he could barely walk.

5 The cyst developed his acetabulum. That's the top part
6 of his hip joint. Continuing record of those hips. And
7 here's what we're looking at. Those are that -- those are
8 the -- the cysts -- the kind of cysts that form from someone
9 working a hip hard.

10 After the surgery look at this, I mean this is -- this is
11 just wonderful. This is what DePuy hopes for: Ride daily and
12 strenuously, do all the walking, lifting involved in normal
13 life, all without pain. He did it for six years. But that's
14 a lot of work and effort on the hip. These are things he did
15 throughout the time that he had his Ultamet hip.

16 But the cysts came back. And they came back not because
17 of metal. They came back because of the pressure that was
18 caused by all his strenuous, really wonderful, accomplished
19 activity.

20 And you will hear an expert come in and tell you that
21 based on the CT scan he can tell you the revision was not due
22 to metal debris, rather it was due to fluid pressure. I don't
23 read that to mean anything, about an expert does.

24 Again, Captain Peterson was revised because of the cyst
25 coming back, not because of any defect in the Pinnacle device.

1 Mr. Klusmann, of all the -- the patients, has the ability
2 to understand and know and choose risk versus benefit and to
3 understand how to deal with doctors. He's the CEO of a
4 hospital. He knows this stuff.

5 DePuy has always warned about the potential for a tissue
6 reaction in a metal-on-metal device. Always warned about
7 that. And his doctor knew about it. You're going to hear
8 from Dr. Heinrich who said I knew that. I knew -- that DePuy
9 didn't tell need to tell me. I knew that long before. It's
10 one of the things I considered in deciding what hip to use.

11 Dr. Heinrich warned Mr. Klusmann. This is from the
12 medical records from Mr. Klusmann where Dr. Heinrich described
13 the risk of surgery. In the very middle of the document you
14 see hypersensitivity.

15 This is no surprise. It wasn't kept secret from anyone.
16 It is a known and expected risk. And Mr. Klusmann signed the
17 consent saying that I understand, I get it, but I want the
18 hip.

19 No question that hypersensitivity was the diagnosis for
20 Mr. Klusmann all throughout his records. Everyone agrees,
21 including the plaintiffs' experts.

22 So at the end of the day we're going to ask you to render
23 your verdict based on the evidence and not based on any
24 emotion that you've heard from -- from plaintiffs' counsel or
25 Mr. Lanier. But the evidence is not one of them was revised

1 because of any defect in the Pinnacle metal hip. They all had
2 individual different reasons for their revisions.

3 Thank you very much.

4 Thank you, Your Honor.

5 THE COURT: Thank you, Mr. Sarver.

6 Ladies and gentlemen, we'll start back at 1:35.

7 The lunch for you is in the jury room.

8 Thank y'all very much. Don't talk about the case.

9 THE COURT SERVICE OFFICER: All rise.

10 (Recess taken at 12:28.)

11 (Proceedings resumed at 1:47.)

12 THE SECURITY OFFICER: All rise, come to order,
13 please.

14 (Outside the presence of the jury.)

15 THE COURT: Okay. Just from what y'all have said
16 I'm assuming Dr. Ekdahl is the first witness, right?

17 MR. LANIER: That's correct.

18 THE COURT: What about exhibits? Have we got any
19 agreements or do I just need to rule on the fly?

20 MR. LANIER: I have shown the exhibits that I plan
21 to use until the next break. Mr. Quattlebaum, I understand
22 there are two exhibits that he has a question about. An
23 objection to.

24 THE COURT: Do y'all agree on some of the others?

25 MR. QUATTLEBAUM: Yes, Your Honor.

1 THE COURT: Ah, thanks, Mr. Quattlebaum. I
2 appreciate that.

3 MR. LANIER: You are objecting to Plaintiff's
4 Exhibit 38?

5 MR. QUATTLEBAUM: Exhibit 38, you will recall from
6 the previous trial is the proposed rule change that's
7 contained in the CFR regarding metal-on-metal products and
8 Mr. Lanier spent considerable amount of time going over that
9 in detail. Our objection is that, number one, it's hearsay.
10 Number two, it's a proposed rule, not a final rule. So it has
11 very little -- has no probative value, but whatever probative
12 value it might have would be substantially outweighed by its
13 prejudicial effect and questioning this witness about
14 something contained in the CFR is beyond the scope of the
15 witness and not proper cross-examination.

16 THE COURT: And?

17 MR. LANIER: And I used it last time against him.
18 It's something that he certainly had notice about, everybody
19 had notice about. It's the FDA findings. It's the rest of
20 the story from what Mr. Sarver put on the opening screen this
21 morning.

22 MR. QUATTLEBAUM: Your Honor, before I go on,
23 Mr. Ekdahl is in the room. If you want him to step outside.

24 THE COURT: Would you?

25 MR. QUATTLEBAUM: Sorry.

1 THE COURT: I'm sorry. I should have recognized
2 him. I didn't see him. My fault.

3 MR. QUATTLEBAUM: Our response to that is it's not a
4 final document, Judge.

5 THE COURT: What's happened by the way on these?

6 MR. QUATTLEBAUM: Nothing. It's not a final.

7 THE COURT: Still pending?

8 MR. QUATTLEBAUM: Yes.

9 THE COURT: The federal government acts like this.
10 Have y'all noticed?

11 MR. LANIER: As a practical matter the FDA did issue
12 a ruling that required drug -- metal-on-metal product
13 manufacturers to go through the PMA process now, and none of
14 them are doing it. So there's no need for this rule to become
15 final until they do.

16 MR. QUATTLEBAUM: I disagree with --

17 THE COURT: You disagree with that interpretation
18 that that's what they're doing?

19 MR. QUATTLEBAUM: I disagree they ever did that.
20 They proposed it, but they have never done it. They have
21 talked about going forward and making such a requirement.

22 THE COURT: So they don't have that shorter way of
23 doing it?

24 MR. QUATTLEBAUM: Well, sort of.

25 THE COURT: Or different way of doing it. Would

1 that be a better term?

2 MR. QUATTLEBAUM: Correct.

3 THE COURT: Okay. But they have not done anything?

4 MR. QUATTLEBAUM: It hasn't happened.

5 THE COURT: How are y'all so disagreeable on that?

6 MR. QUATTLEBAUM: It's just our nature.

7 THE COURT: Well, yes, that's true, but --

8 MR. LANIER: It's the way we're wording it. The
9 reason it hasn't happened is because they pulled the product
10 off the market. If they were going to continue with the
11 product, then the FDA would have said you have to do a PMA.

12 MR. QUATTLEBAUM: We disagree.

13 THE COURT: All right. I will think about this.
14 Don't talk to him about it until we take a break.

15 I'm assuming he's not a five-minute witness.

16 MR. LANIER: He's not a five-minute witness, but
17 that was pretty early on, Your Honor.

18 THE COURT: Pretty early?

19 MR. LANIER: Because I used it in the last trial
20 without any trouble.

21 THE COURT: I understand that.

22 MR. LANIER: I know.

23 THE COURT: I've become a better judge since then.

24 (Laughter)

25 MR. LANIER: I understand, Judge.

1 THE COURT: I've read some law since then.

2 MR. LANIER: Okay.

3 THE COURT: But I will look at it and let you know.

4 MR. LANIER: Thank you, Your Honor.

5 The other one is Plaintiff's Exhibit 10 that we're going
6 to offer, which is a PowerPoint by one of their consulting
7 doctors, Dr. Fehring. I showed a slide from it in opening.
8 It's the seduction Powerpoint.

9 THE COURT: You think?

10 MR. QUATTLEBAUM: First of all, it's hearsay.
11 Second, if somebody needs to talk about it, it would be
12 Dr. Fehring.

13 Third, it occurred sometime -- We're not sure exactly
14 when, but certainly after all of the implants that are in
15 existence in this case -- and, frankly, probably after
16 Ultamet -- was withdrawn from the market. So whatever
17 probative value it has would be only probative in context of
18 Dr. Fehring. And whatever effort it would have in -- with
19 Mr. Ekdahl would be substantially outweighed by the confusion
20 it would cause because he didn't create the document.

21 THE COURT: Okay.

22 MR. LANIER: We've got the deposition to prove up
23 the document and to prove that this was a speech that's been
24 given repeatedly by the company to prove that this is, in
25 fact, a fellow who has been paid by DePuy who worked on the

1 project, and he's looking back historically and giving his
2 assessment.

3 THE COURT: What is this document?

4 MR. LANIER: The PowerPoint presentation that the
5 doctor has given at continuing medical seminars.

6 THE COURT: Is he a DePuy paid doctor?

7 MR. LANIER: Yes, he is.

8 THE COURT: Has he made it at DePuy events?

9 MR. LANIER: Yes, he has.

10 THE COURT: What are you going to ask --

11 MR. LANIER: Did you say has he made this
12 presentation at DePuy events?

13 THE COURT: Yes.

14 MR. LANIER: I don't know that.

15 THE COURT: Absolutely?

16 MR. LANIER: He tells everybody -- You will see at
17 the beginning of it you'll see he lists himself as someone who
18 has the interest -- On the conflict of interest sheet, Your
19 Honor, he will say his disclosure is royalties, DePuy and a
20 J&J consultant. And he puts that at the start of the
21 presentation himself.

22 THE COURT: Is Fehring coming?

23 No?

24 MR. LANIER: We've got him by deposition, your
25 Honor, but not live.

1 THE COURT: But he's going to be played?

2 MR. LANIER: Yes, Your Honor

3 MR. QUATTLEBAUM: He will either be played or live.

4 He testified about this extensively in his deposition.

5 He was never an agent of DePuy when he gave that presentation.

6 It's not clear when he gave it. He said I think I gave it to

7 residents. I think I might have been in a debate with another

8 doctor about it when I gave it. Mr. Lanier showed him that

9 very slide, and he said you're taking this out of context and

10 dramatizing it. I remember that from the deposition.

11 So it was never an admission by DePuy because he's not an
12 agent of DePuy.

13 THE COURT: Okay. Overrule your objection to this
14 one.

15 The other one I'll think about.

16 What else?

17 MR. LANIER: Those are the only two in contention
18 for the next hour or two, Your Honor.

19 THE COURT: Here's what I propose to say to the
20 jury, the exhibits that they don't offer are automatically in.
21 I'm not making the lawyers go -- They have been cooperative,
22 and there will be a number of those exhibits. There may still
23 be fights about exhibits, but they will come up as they
24 actually come up, but otherwise that's -- that's -- it's just
25 saving some time. Is that okay with you?

1 MR. QUATTLEBAUM: Yes, Your Honor.

2 With regard to saving time, I need some advice from the
3 court.

4 There will be a lot of exhibits in this case that will
5 postdate the implant of the plaintiff, that will go to the
6 issue I presume of whether there should have been some notice
7 to DePuy or some other purpose and the postdating or a
8 statement by DePuy --

9 THE COURT: I'm not sure what you're saying. They
10 were postdated or they occurred after the implants?

11 MR. QUATTLEBAUM: Thank you for that clarification.
12 They were not postdated. They occurred after the implant
13 occurred, and so they could not have affected the decision
14 making of the surgeon who implanted the device. I don't want
15 to have to stand up every five minutes and make that
16 objection, if I can help it. May we have a continuing
17 objection for that purpose for documents that are dated that
18 occurred after the event of the implant?

19 THE COURT: Do it once and that will be fine. How's
20 that?

21 MR. QUATTLEBAUM: Thank you, Your Honor.

22 THE COURT: I mean, I know that's not perfect. I'm
23 going to let that in, but do it once because I think the jury
24 needs to hear it once, and then I will make it clear on the
25 record, but remind me to do it, that you don't have to do it

1 otherwi se.

2 MR. QUATTLEBAUM: Judge, don't strike me down if I
3 happen to make it more than once.

4 THE COURT: I can't promise that, on the strike you
5 down thi ng.

6 (Laughter)

7 MR. QUATTLEBAUM: All right.

8 THE COURT: I mean, all y'all are in line of danger,
9 from both sides. You just are. You're lawyers.

10 MR. QUATTLEBAUM: I feel like I'm in a canoe in a
11 thunderstorm. You might get struck by lightning.

12 THE COURT: I would say a rubber raft, and I mean
13 like my grandkids have, not the real good kind like the
14 milit ary. That's what I would say.

15 Yes, I know. My friends say, yes, federal court is a
16 place where bad things happen to lawyers. That's what my
17 fri ends say.

18 MR. QUATTLEBAUM: To good peopl e.

19 THE COURT: But I will try to be nice to you.

20 Here we go.

21 And fai r.

22 All right. So how many other exhibits are there on him?

23 MR. LANIER: Your Honor --

24 THE COURT: 30, 40, 50?

25 MR. LANIER: Yes, Your Honor.

1 THE COURT: Okay. All right.

2 Anything else?

3 I want to make sure -- Mr. Powell, usually there's
4 something you have kind of the last Columbo word.

5 MR. POWELL: I do not have anything else right now,
6 Your Honor.

7 THE COURT: Thank you, Mr. Columbo. I appreciate
8 that.

9 All right. Let's bring them in.

10 (Jury enters the courtroom.)

11 THE COURT: If the sandwiches were cold, that was my
12 fault.

13 All right. We're ready to call our first witness.

14 MR. LANIER: Thank you, Your Honor.

15 As an adverse witness I would call the DePuy Johnson &
16 Johnson at least president for a while Andrew Ekdahl to the
17 stand.

18 THE COURT: Mr. Ekdahl, how are you today?

19 MR. EKDAHL: I'm fine, thank you.

20 THE COURT: Good to see you.

21 MR. EKDAHL: Thank you.

22 THE COURT: Would you raise your right hand.

23 Oh, Ronnie, you're going to swear him in. I'm sorry.

24 (Witness sworn.)

25 THE COURT: Have a seat next to me, Mr. Ekdahl.

1 There is water.

2 Is there anything else you need down there?

3 MR. EKDAHL: I'm fine.

4 THE COURT: You know how to talk into that
5 microphone?

6 MR. EKDAHL: Yes, sir.

7 MR. LANIER: May I begin, Your Honor?

8 THE COURT: Yes.

9 DIRECT EXAMINATION

10 BY MR. LANIER:

11 Q. Mr. Ekdahl, good afternoon.

12 A. Good afternoon.

13 Q. I want to make sure that the jury knows how to spell your
14 name as much as me.

15 You are Andrew, can you spell your last name, please?

16 A. Certainly. E-k-d-a-h-l.

17 Q. Mr. Ekdahl, what is your current job, today?

18 A. My job today is the president of Ethicon Surgical Care.

19 Q. And Ethicon Surgical Care is another Johnson & Johnson
20 subsidiary?

21 A. That's correct.

22 Q. And they also make medical devices?

23 A. That's correct.

24 Q. All right. At one point in time you were the president
25 of DePuy, the company that makes the hips, right?

1 A. Yes, I was the president of DePuy Synthes Joint
2 Reconstruction. Correct.

3 Q. Mr. Ekdahl, before we get into that, were you here or in
4 one of the overflow courtrooms where you were listening to the
5 opening statements this morning?

6 A. No, sir. I arrived during the break.

7 Q. Did you have an opportunity to hear anything at all --
8 and I'm not asking you about what lawyers have told you, but
9 to hear anything at all about the various themes that were set
10 forward by Mr. Sarver on behalf of DePuy?

11 A. No, sir.

12 Q. All right. I'd like to look at some of these themes, at
13 least as I heard them, and see if you and I can agree upon
14 some aspects related to them. Okay?

15 A. Okay.

16 Q. I'm calling them J & J/DePuy excuse. That's probably a
17 bit argumentative of me. I'll at least say these themes.
18 Okay?

19 Do you follow me?

20 A. I follow what you have written.

21 Q. And I want to look at those, but I also want to look at
22 the truth and see if we can come to an agreement about some
23 truth on such issues. Fair?

24 A. Okay.

25 Q. All right. First, innovation is important.

1 Now, you believe that, don't you?

2 A. Innovation is important, yes, I do.

3 Q. But you also would agree with me that innovation must be
4 done responsibly, right?

5 A. Yes.

6 Q. And you would also agree with me that innovation without,
7 for example, proper testing, innovation minus proper testing,
8 can be a formula for disaster, can't it?

9 A. I would use appropriate testing.

10 Q. All right --

11 A. And I don't know that --

12 Q. -- you would say appropriate instead of proper?

13 A. And I'm not sure that that is a disaster.

14 Q. It can be. You might look at it, might be, might not be,
15 right?

16 A. May or may not be, but I don't -- I wouldn't use
17 disaster.

18 Q. Have you looked at some of the problems that some of the
19 plaintiffs have had in this case?

20 A. I'm not familiar with the plaintiffs in this case.

21 Q. Have you considered what's happened to Mr. Klusmann or
22 some of the others who have lost a lot of tissue and muscle
23 and tendons and whose bodies have been wrecked?

24 A. I'm not -- I don't know what's happened to each of --

25 Q. All right.

1 A. --to these of these plaintiffs.

2 Q. All right.

3 Next thing.

4 No hip implant is perfect.

5 Now, you and I both know that to be true, don't we?

6 A. I would say no medical device is perfect.

7 Q. Okay. Well, what other kind of hip implants are there?

8 A. Well, there could be a trauma hip implant, but I'm saying
9 that there is -- no medical device is perfect, and hips are
10 medical devices.

11 Q. Okay. So you would agree with us that no hip implant is
12 perfect.

13 I mean, I think that's one of the big arguments that
14 y'all have been making.

15 A. I think that we have -- keep going.

16 Q. Okay.

17 Now, while no implant is perfect, would you also agree in
18 front of the jury that perfection is not the standard. Right?

19 A. Perfection is not the standard?

20 Q. Right.

21 A. I -- I don't know how to re-- I can't agree to that.

22 Q. Well, what I mean by that is we're not -- no one in this
23 case is suggesting that hip implants need to be perfect before
24 they're sold. We're just saying sell the better ones and tell
25 us if you're selling one that's worse. Right?

1 A. I don't -- I -- I'm struggling to follow what you're --
2 how you're positioning that. I'm sorry.

3 Q. There's -- there's not a perfect car that's made. Would
4 you agree with me on that?

5 A. Yes, I would agree with you.

6 Q. But that doesn't mean you can make Ford Pintos that are
7 going to explode when people get hit in it rear if they get
8 hit at just the right angle at just the right time? Right?

9 A. Okay.

10 Q. Okay. So while no hip implant is perfect that doesn't
11 mean you guys aren't responsible for making one that's
12 reasonably safe and -- and reliable, right?

13 You still got responsibility, don't you?

14 A. Yes, we have responsibilities.

15 Q. All right. Every hip implant has risks.

16 We kind heard that, at least by my hearing this morning.
17 You follow what I mean by that?

18 A. I think every hip implant has some level of risk, yes --

19 Q. All right.

20 A. -- that is correct.

21 Q. Would you agree with me that the risks must be reasonable
22 and they must be clearly -- must be reasonable and clearly
23 disclosed. Agreed?

24 A. I don't think you can disclose every single risk.

25 Q. If you know the risk you ought to disclose it, right?

1 A. I think it depends on that particular risk.

2 So I can't -- I don't know how you can disclose every
3 single risk. There are risks that are known in the orthopedic
4 community that I don't know if you need to disclose.

5 Q. So your position is the risks must be reasonable --
6 you'll agree with that part, right? Every implant has got
7 risks but they must be reasonable?

8 A. I agree every implant has risks.

9 Q. And those risks should be reasonable, right?

10 A. Yes.

11 Q. But you don't agree that they should be clearly
12 disclosed. Just the -- which ones should be?

13 A. I don't know. I'm -- I haven't thought that through I
14 guess while we're sitting here.

15 Q. You've worked on some of the materials that DePuy put out
16 for its Pinnacle hip. You personally worked on them, didn't
17 you?

18 A. I was among the team that worked on them, yes.

19 Q. You had interactions with a number of the writers for
20 some of those brochures and materials, didn't you?

21 A. I would have, yes, along with --

22 Q. Not "I would have," you did.

23 A. I did, yes.

24 Q. Okay.

25 You were involved in the decisions of what risks would be

1 disclosed and which ones would not, weren't you?

2 A. I don't believe that, no.

3 Q. Are you sure?

4 You didn't edit the technical monograph 2002?

5 A. I don't believe I did.

6 Q. Okay.

7 At any rate, which risks do you believe as a manufacturer
8 you had a duty to disclose to the doctors and patients for
9 your metal-on-metal implants?

10 A. That would be a conversation that would happen between
11 our regulatory team and the FDA on what are required
12 disclosures. I don't know them.

13 Q. Wait. Wait. Wait.

14 You're suggesting that the FDA tells you what you have to
15 disclose in terms of risks?

16 A. I'm saying that is a dialogue between a device
17 manufacturer and the FDA.

18 Q. It's actually something that the device manufacturer has
19 responsibility for before it sells a device, to disclose the
20 risks. Right?

21 A. In -- based on what -- based on guidance from the FDA.

22 Q. And you're not able to tell us which ones you believe
23 should be disclosed and which should not?

24 A. Off the top of my head, no.

25 Q. All right.

1 Next. There are no guarantees.

2 Y'all don't guarantee the performance of your
3 metal-on-metal hip implants, right?

4 A. I'm sorry, what do you mean "guarantee," in a sense of
5 what?

6 Help me define "guarantee."

7 Q. In a sense that we guarantee this is going to work or
8 your money back.

9 A. That's correct.

10 Q. Because if it doesn't work y'all just sell 'em another
11 one, don't you?

12 A. We -- sell -- what do you mean "sell them another one"?

13 Q. If a person's got a Pinnacle metal-on-metal hip in and
14 the hip fails, y'all just sell them another one, don't you?

15 A. The revision may or may not be with a DePuy product. It
16 might be with somebody else's product.

17 Q. Okay. But y'all certainly pursued selling more, didn't
18 you? The revision market was something you sought after,
19 right?

20 A. Yes. It's an important hip market.

21 Q. There are no guarantees.

22 But would you agree with me that DePuy needs to be
23 responsible for its products?

24 Would you agree?

25 A. Yes.

1 Q. And would you agree with me that not only -- and I say
2 is, let's say must be.

3 And not only must they be responsible but they need to be
4 accountable if the product is defective, right?

5 A. If the product is defective?

6 Q. Right.

7 Can I get an agreement from you?

8 A. If the product is defective --

9 Q. Yes.

10 A. -- should we be accountable?

11 Q. Right.

12 A. If the product is defective, yes.

13 Q. Okay.

14 Next thing.

15 There's something wrong with the patient.

16 Someone had a cyst, someone's got some diagnosis that's
17 basically so rare it's almost unheard of in someone like that,
18 saying there's something wrong with the patient, that
19 shouldn't be done lightly, should it?

20 A. I guess I don't know the context. It would be -- I would
21 look at that and say that is a case-by-case statement.

22 Q. But typically isn't that something -- if you want to know
23 there's a problem with a patient wouldn't you typically go to
24 a patient's doctor to ask them?

25 A. Would I?

1 Q. Yes.

2 A. I would want to understand -- I guess I would want to
3 understand the context of that particular statement,
4 understand if I can agree to that or not.

5 Q. But before the company comes in before front of the jury
6 and just says, oh, there's just some unique problem with each
7 of these five plaintiffs, a different one with each, and we've
8 hired doctors to come in here and say it, isn't it appropriate
9 just to ask the doctors who treat the patients?

10 MR. QUATTLEBAUM: Excuse me, Mr. Lanier.

11 Your Honor, I object. It's just an argumentative
12 question. It's not a question of fact. It's asking for some
13 kind of legal opinion about what takes place in the courtroom.
14 Mr. Ekdahl is not a lawyer.

15 THE COURT: Overrule your objection.

16 THE WITNESS: It's a patient-by-patient conversation
17 that I'm not even a -- I'm not a surgeon, I can't answer for
18 that.

19 BY MR. LANIER:

20 Q. Have you seen the J & J strategy memo that says blame the
21 patient in the process of trying to handle these types of
22 problems with ASR?

23 A. "Blame the patient"?

24 Q. Yeah.

25 A. No.

1 Q. Would you agree with me at least, you can't just blame
2 the patient -- wait. Let me ask it this way?

3 MR. LANIER: Your Honor, if I could strike that and
4 get another run at it.

5 BY MR. LANIER:

6 Q. Would you agree with me that it's not right to blame the
7 patient if it is in fact a problem with your product? Right?

8 A. If it's a product issue -- I'm sorry, I need you to
9 repeat your statement, sir.

10 Q. Yes.

11 If it's a problem with -- problem with the product
12 doesn't blame the patient. Fair?

13 A. Well, if it's a problem with the product or is it a
14 known -- I guess a known issue with a particular product.

15 I guess I don't know how you define "problem," so it's
16 very difficult to even agree with that.

17 Q. Okay. We'll come back to it then.

18 ASR and Pinnacle are different.

19 Now, we didn't hear that that much yet, but I want to
20 talk to you about it with the jury.

21 ASR, you know what that product is, don't you?

22 A. I'm sorry, do I?

23 Q. Yes.

24 A. Yes.

25 Q. You were hands-on with that product, weren't you?

1 A. I'm sorry, what do you mean "hands-on"?

2 Q. You had a very deliberate involvement over the hip unit
3 when that product was out, right?

4 A. Yes. I was among the people in our hip business when
5 that product was made available, correct.

6 Q. And one way we might describe it, instead of being four
7 pieces like the Pinnacle, the ASR was three pieces, right?

8 A. I'm sorry, I can't -- forgive me, I can't see what you
9 even have in your hand.

10 Q. Oh, I'm sorry. Here, I'll put it right here for you.

11 A. I'm not sure you've got the correct products.

12 Q. All right. The DePuy Pinnacle system has four pieces,
13 correct?

14 A. Generally.

15 Q. You have a stem that goes in the thigh bone?

16 A. In the femur, correct, yes.

17 Q. "Femur" is technical word for the thigh bone, right?

18 A. Yes.

19 Q. You've got the cup that goes in the pelvis, correct?

20 A. In the prepared acetabulum, yes.

21 Q. And the jury can see the coating on both the stem and the
22 cup. That's because that's in touch with bone and hopefully
23 will grow into the bone, right?

24 A. It's designed for bone to grow into it, correct.

25 Q. Okay. There are holes in the cup because sometimes when

1 the doctor puts the cup in there he may put in screws as well
2 to hold it, right?

3 A. That's correct.

4 Q. And then in the Pinnacle system you can put a liner
5 inside that cup so that the ball that goes on the stem has
6 something to rub on. Right?

7 A. Yeah. That's the articulating surface, correct.

8 Q. And with Pinnacle you can do it with a metal liner or you
9 can put in a plastic or polyethylene liner, correct?

10 A. That is correct.

11 Q. Now, ASR had a stem, right?

12 A. It was ASR XL, yes.

13 Q. Yes. And ASR -- which is the one you sold in the U.S.?

14 A. Yes. It's the one available in the United States, ASR
15 XL.

16 Q. Had a ball, correct?

17 A. A different ball than the one you've got there.

18 Q. Yeah. This is an MSpec ball, but it had a ball that went
19 on the edge of the stem, right?

20 A. Correct.

21 Q. But instead of having two pieces, the ASR had just one
22 piece and the liner was built into the shell, correct?

23 A. That is correct.

24 Q. And the ASR was also metal-on-metal, wasn't it?

25 A. Yes, it was.

1 Q. And the ASR was signed off on or allowed to be used by
2 the FDA, correct?

3 A. The ASR XL was a 510(k) cleared product in the United
4 States.

5 Q. Great. We'll get to some of those details perhaps later
6 with the jury. But for our purposes right now let's see if we
7 can agree to this?

8 Both -- the FDA approved the ASR XL because DePuy swore
9 to the FDA that ASR and the Pinnacle metal-on-metal were
10 substantially equivalent on safety and efficacy. Right?

11 A. I don't know what was stated in the 510(k).

12 Q. That's what a 510(k) states, substantial equivalence in
13 safety and efficacy. Did you not know that?

14 A. Well, I don't know -- I think it was that the Pinnacle
15 metal-on-metal was among the devices that were substantially
16 equivalent. It wasn't only Pinnacle metal-on-metal as
17 substantially equivalent to ASR. There was a -- there's a
18 group of devices.

19 Q. And I'm not fussing that with you, but one of the devices
20 that DePuy swore was substantially equivalent in safety and
21 efficacy was the Pinnacle metal-on-metal, the Ultamet. Right?

22 A. That was among the devices that were substantially
23 equivalent.

24 Q. And so we're clear with the jury, your company issued a
25 re-call of the DePuy ASR, didn't it?

1 A. Yes.

2 Q. It issued a re-call because ASR is a defective product,
3 correct?

4 THE COURT: Stop just a second.

5 Go ahead.

6 MR. QUATTLEBAUM: Your Honor, we would object to any
7 evidence regarding the ASR re-call. The ASR is a different
8 product, not at issue in this case.

9 THE COURT: Overruled.

10 MR. QUATTLEBAUM: And may that be a continuing
11 objection?

12 THE COURT: Yes, sir.

13 MR. QUATTLEBAUM: Thank you, Your Honor.

14 BY MR. LANIER:

15 Q. The ASR was re-called because of its high revision rate,
16 correct?

17 A. The revision rate did not meet our clinical -- didn't
18 meet the clinical requirements of the market.

19 Q. Well, that's -- that's technical language for saying it's
20 too high and was hurting too many people, right?

21 A. The revision rate did not meet the clinical requirements
22 of the market.

23 Q. Which is very dressed-up language which means to ordinary
24 people there were too many revisions and so the product was
25 hurting too many people. Right?

1 A. There were too many revisions, correct.

2 Q. And a revision does hurt people. That's not a good
3 thing, right?

4 A. Revisions are not good, correct.

5 Q. Okay.

6 So DePuy re-called the ASR. Do you remember when?

7 A. So I wasn't -- I was not living in the United States at
8 the time of the re-call, so I believe it was August of 2010.
9 I believe.

10 Q. Yeah. No, you're right.

11 And what the company did when they re-called ASR is they
12 told the sales force try to talk the doctors that were using
13 ASR into using Pinnacle metal-on-metal and just move them from
14 one to the other. Right

15 A. It was to get the surgeons to understand the benefits of
16 Pinnacle metal-on-metal, correct, that the device that was
17 performing very well on the market.

18 Q. Actually, as of August 2010 did you not know that all of
19 your surgeons that you used that you were paying money to had
20 quit using the product? Quit using Pinnacle metal-on-metal?

21 A. I don't believe they all had.

22 Q. So your belief is that as of August 2010, you say -- I'll
23 put A.E. as your initials -- you say Pinnacle metal-on-metal
24 was performing -- let's see what you said.

25 "Very well."

1 And that's your testimony to this jury?

2 A. Yes.

3 Q. Okay. We'll get into that in a little bit.

4 This argument I expected to hear, but I did not hear it,
5 so we're going to set it aside for a moment.

6 The FDA let us sell it.

7 Again, the FDA allowed the company to sell Pinnacle
8 metal-on-metal, right?

9 A. The FDA cleared Ultamet metal-on-metal for use in the
10 United States, that's correct.

11 Q. But so the jury understands, the FDA never tested the
12 product, did it?

13 A. That's not the role of the FDA.

14 Q. Excuse me, that wasn't my question, sir.

15 The FDA never tested the product, did it?

16 A. It's not the role of the FDA.

17 Q. I understand that, sir.

18 But the FDA does at time test products and at times
19 orders the testing of products. You understand that, don't
20 you?

21 A. I don't believe the FDA tests products.

22 Q. You did not know that the FDA sometimes on their own,
23 it's not often, but rarely tests a product or pharmaceutical
24 device?

25 A. To the best of my knowledge I did not know that.

1 Q. All right. Well, then regardless, you'll agree with me
2 the FDA never tested Pinnacle, did they?

3 A. The FDA wasn't going to test Pinnacle.

4 Q. So that means they never -- sir, this simple truth.
5 Simple truth: FDA never tested Pinnacle, true?

6 A. True.

7 Q. All right.

8 Simply truth: The FDA relied on the information given to
9 it by DePuy and Johnson & Johnson, right?

10 A. By DePuy, correct.

11 Q. You've heard the expression garbage in/garbage out,
12 haven't you?

13 A. I've heard that, yes.

14 Q. Because the -- the decision that's going to be made is
15 only as good as the data given to the decisionmaker. Fair?

16 A. Fair.

17 Q. So when the -- when -- when your company is swearing that
18 ASR is substantially equivalent in safety and efficacy to
19 Pinnacle, it -- your company got Pinnacle approved by doing
20 much the same thing, right?

21 A. I -- I disagree with that.

22 Q. No. No. No.

23 Pinnacle got approved under 510(k) is what it's called,
24 right?

25 A. Yes. Pinnacle Ulamet was a 510(k), correct.

1 Q. And what 510(k) says is you can get it approved for sale
2 if you will swear that it's substantially equivalent in safety
3 and efficacy to another product that's being sold.

4 A. Or group of products.

5 Q. Right.

6 Correct?

7 A. Yeah, so --

8 Q. And that's how Pinnacle got approved, through this 510(k)
9 process, didn't it?

10 A. That's how almost every medical device in the United
11 States is approved.

12 MR. LANIER: Objection, nonresponsive.

13 THE COURT: Sustained.

14 BY MR. LANIER:

15 Q. Can you answer my question, sir?

16 A. Can you ask it again, please?

17 Q. That's how Pinnacle got approved through the 510(k)
18 process, correct?

19 A. Yes. In working with the FDA, the FDA cleared Pinnacle
20 through the 510(k) process.

21 Q. Because your company swore that Pinnacle was
22 substantially equivalent to the Ultima, didn't it?

23 A. Among other things, yes.

24 Q. The Ultima got pulled because of its failures, didn't it?

25 A. No. Under no circumstance.

1 Q. What?

2 A. No. No.

3 Q. Did you see the failures over in England?

4 A. Yes.

5 Q. Did you read the report?

6 A. Yes.

7 Q. And you don't think it says that metal-on-metal particles
8 were the reason for Ultima failures?

9 MR. QUATTLEBAUM: Your Honor, we would object to
10 questions about Ultima. Different product, different
11 application, and not the product at issue in this trial.

12 THE COURT: Overruled.

13 MR. QUATTLEBAUM: And, Your Honor, may I also
14 supplement my earlier objection on ASR as being subsequent
15 remedial measure?

16 THE COURT: I didn't hear the very last thing. I
17 apologize.

18 MR. QUATTLEBAUM: Subsequent remedial measure
19 objection on my earlier ASR objection as well.

20 THE COURT: You're adding to the one I said you
21 didn't have to make?

22 MR. QUATTLEBAUM: Yes.

23 THE COURT: Okay.

24 Overrule that, too.

25 BY MR. LANIER:

1 Q. Go ahead, sir, if you would answer it.

2 Do you remember it?

3 A. I'm sorry, I don't.

4 Q. That's okay.

5 I said, you don't think that the report on the Ultima
6 says that part of the failure was because of the
7 metal-on-metal articulation?

8 A. I don't recall exactly what that report says.

9 Q. All right. There's probably a better witness for me to
10 thrash through that than you anyway; would you agree with me?

11 A. I think there probably is.

12 Q. All right. I'll wait for that.

13 Next subject I want to talk to you about from
14 Mr. Sarver's opening:

15 Mr. Sarver suggested to the jury that DePuy's one goal is
16 to produce products to help people.

17 A. I would agree with that.

18 Q. Actually, DePuy's goal is I'm sure in part to have
19 products that help people, but the goal is to make money
20 selling those products, right?

21 A. We wouldn't be successful if we didn't have products that
22 worked and helped people.

23 Q. Actually, sir, I'm not fussing that at all. But your
24 company does have products that haven't worked that y'all have
25 sold anyway and you've had to quit selling, right?

1 A. Yes.

2 Q. Okay. My point is, what your company has done -- and the
3 jury is going to get to hear all this -- do you know Mimi
4 Drumwright, that lady right there back in the corner.

5 Mimi, would you stand up, please?

6 Do you know Dr. Drumwright?

7 A. I do not.

8 Q. She'll be the witness right after you. She's going to
9 testify about the marketing in this case and how it was done.
10 Now you're a marketing fellow, aren't you?

11 A. I've worked in marketing, that's correct.

12 Q. Well, not just worked in it, that's how you got your feet
13 wet, right?

14 A. I would disagree. I began my career in sales.

15 Q. Sales is different than marketing?

16 A. They're different requirements, different professions,
17 yes.

18 Q. Okay. So you're in -- you would at least agree with me
19 you're in sales and marketing, fair?

20 A. I would say that my career has been in sales and
21 marketing and general management.

22 Q. So if we look at you as worldwide president for this
23 DePuy Synthes Joint Reconstruction and DePuy Orthopaedics,
24 that was a job title you used to have before you got moved
25 over to another J & J company, right?

1 A. That's correct.

2 Q. But you weren't qualified to head this place up because
3 you were an orthopedist or a joint man, right?

4 A. I'm sorry. I don't understand that.

5 Q. Your qualifications to be president didn't come about
6 because you were orthopedically trained. That's not what your
7 training was, was it?

8 A. Are you asking me am I an orthopedic surgeon?

9 Q. Sure.

10 A. I am not an orthopedic surgeon --

11 Q. Well, I won't ask it -- I'll go this way.

12 You're not only -- are you an orthopedist? The answer is
13 no.

14 But are you a licensed medical doctor? The answer to
15 that is no as well, isn't it?

16 A. I am not a licensed medical doctor. That's correct.

17 Q. And I'm just trying to figure out first what kind of
18 person has made it all the way up from the bottom to the top
19 of this company. You don't have a science background, do you?

20 A. I do not have a degree in science.

21 Q. You don't have a pharmacy background, do you?

22 A. I do not.

23 Q. You don't have a biological engineering background, do
24 you?

25 A. No.

1 Q. You don't have an FDA background, do you?

2 A. I do not.

3 Q. Your background is in sales and marketing, fair?

4 A. Sales and marketing and general management, yes, that
5 would be fair.

6 And general management.

7 Q. By the same token, we can look at DePuy as a company and
8 not just look at the man who is president. DePuy doesn't even
9 have an orthopedist that works for it. DePuy Orthopaedics
10 doesn't have an orthopedist working for it, does it?

11 A. Today we do.

12 Q. I'm talking about back in this hip time. For the decade
13 of 2010, 2012, 2013, there wasn't an orthopedist employed at
14 the company, was there?

15 A. I'd have to go back and look, but I believe there was.
16 But I'd have to go back and look.

17 Q. What was his name or her name?

18 A. Well, Rodrigo Diaz I believe is an orthopedic surgeon.

19 Q. Rodrigo Diaz isn't even licensed in the United States of
20 America.

21 A. No, I understand that.

22 Q. All right. How about there was no orthopedist working
23 for -- By the way, what was Mr. Diaz's job title?

24 A. I believe he was a -- Oh, I can't remember off the top of
25 my head. I believe he was medical director.

1 Q. So you think Dr. Rodriguez (sic) --

2 A. I believe he was a medical director.

3 Q. Was a medical director.

4 And do you know where he got his medical degree from?

5 A. Off the top of my head I don't, no.

6 Q. Okay. But you believe he was also an orthopedist?

7 A. I believe so. Going from memory, yeah.

8 Q. And you think he was a licensed medical doctor?

9 A. I believe so.

10 Q. But not in America?

11 A. Not in the United States, correct.

12 Q. Okay. Fair enough.

13 Now, in this regard, sir, if we look, for example, in a
14 bit more detail at you, and then we'll come back and look at
15 the rest of the company. I've tried to work out your work
16 history for the jury so they can see it while you talk about
17 it.

18 You rose from the top starting out at some humble
19 beginnings, fair? You started out at ground level, worked
20 your way up, right?

21 A. Yeah. I had an entry level opportunity in orthopedics
22 after some other jobs after college.

23 Q. Graduated from college in '84 and you started doing some
24 sales work for Proctor and Gamble between '84 and '87,
25 right?

1 A. That's correct.

2 Q. And when I said you had sales background and you said
3 marketing, I thought you did start out at sales at Proctor and
4 Gamble, didn't you?

5 A. Yes.

6 Q. And then you went to McKim Advertising and did some sales
7 work for them?

8 A. It was a marketing job.

9 Q. Fair enough. And then you started working for Johnson &
10 Johnson Medical Products --

11 A. Yes.

12 Q. -- for two years.

13 And then from there you went on and you became what's
14 called a distributor, correct?

15 A. That is correct.

16 Q. Now, as a distributor -- the jury is going to learn about
17 this more with the Pinnacle. A distributor is one of those
18 folks that goes to the doctors regularly and gives 'em
19 information and provides 'em with product and ultimately tries
20 to convince the doctor to use more product, right?

21 A. And works with the doctor, yes.

22 Q. For example, in hip arena the distributor would go into
23 surgery with the doctor and bring a bunch of DePuy parts to
24 give the doctor, right?

25 A. After the surgeon prescribes the use of a product, the

1 distributor or a sale consultant brings those products to the
2 operating theater, that's correct.

3 Q. All right. And you did that for seven years.

4 A. Yes.

5 Q. And then you got moved over to the hip department in
6 1999. Correct?

7 A. Yes.

8 Q. And from '99 to 2001 you were the product director. You
9 moved up to group product director. Right?

10 A. Yes.

11 Q. Now, when you're the product director, you're not that
12 because you have you're an orthopedist or because you have
13 science, are you?

14 A. No.

15 Q. The product director was the best salesman they had
16 because you were trying to develop products that you could
17 sell. Right?

18 A. No. We were trying to develop -- work with the R&D
19 organization to meet unmet clinical needs.

20 Q. Well, actually, sir, as a product director you're trying
21 to find the product that will help you get market share and
22 will make the company -- that are sellable.

23 That's the goal, right?

24 A. To do that requires a product that's meeting an unmet
25 need in the market.

1 Q. Then you became the director of hip marketing, correct?

2 A. Correct.

3 Q. Then you became the vice president for marketing in the
4 United States. Right?

5 A. Correct.

6 Q. Vice president for the United States hip marketing and
7 worldwide vice president for marketing and business strategy
8 on hips. Correct?

9 A. Actually, I was not responsible for hips at that point in
10 time.

11 Q. All right. So no hips reported to you when you were vice
12 president for marketing and business strategy?

13 A. No, sir.

14 Q. All right. That one is minus hips. The earlier ones,
15 obviously hip related, right?

16 A. Generally, yes.

17 Q. And then you became the franchise vice president for the
18 European, Middle East and Asian markets, right?

19 A. The A is Africa.

20 Q. A is Africa?

21 Thank you.

22 So it's Europe, Middle East and Africa?

23 A. Correct.

24 Q. And then you became the president of DePuy Orthopaedics
25 and worldwide president of DePuy Synthes after that. Correct?

1 A. That's correct.

2 Q. Now, sir, not only do you approach this as someone who is
3 sales oriented, but wouldn't you agree with me the whole
4 company by and large is much more heavily weighted on sales
5 and marketing than it is on research and development?

6 A. What do you mean "heavily weighted"?

7 Q. Well, that's a good question.

8 Let's look at it this way.

9 Is DePuy a science company? Or is it more marketing and
10 sales?

11 Marketing and sales. Whose got the president of the
12 company?

13 Where'd you come from?

14 Which side of this coin? Line.

15 A. Sales and marketing.

16 Q. All right. Employees. Who's got the most employees,
17 marketing and sales or science?

18 A. Well, if you combine sales and marketing, then we have a
19 larger sales and marketing organization.

20 Q. And we'll combine for science R&D, research and
21 development. You've still got more in sales, in marketing,
22 don't you?

23 A. Yeah. Because of the need to cover the -- cover the
24 surgical cases in the market, that's correct.

25 Q. Budget. Who gets the most money, marketing and sales or

1 science?

2 A. The budget for marketing is smaller than the budget for
3 science. Absolutely. But if you add sales to that, the sales
4 budget will be larger.

5 Q. So the marketing and sales budget is larger than the
6 science budget, right?

7 A. That's correct.

8 Q. And as an aside, since you want to throw in extra
9 information, just for the jury to know, some of the research
10 and development budget, the science budget, is actually being
11 spent on marketing anyway, right?

12 A. Perhaps some of it, yes.

13 Q. Well, for example, let me show you what we have marked as
14 Plaintiff's Exhibit 3500.

15 MR. LANIER: Your Honor, I have given a copy of this
16 to opposing counsel before we began. I don't think there are
17 any objections to it. I know you told me we don't need to
18 offer it. Do you want me to give a copy to the witness or am
19 I just okay displaying it.

20 THE COURT: If he's going to be asked questions
21 about it, he needs it.

22 MR. LANIER: May I approach him, Your Honor?

23 THE COURT: Sure. Sure.

24 MR. LANIER: Thank you.

25 BY MR. LANIER:

1 Q. Do you have a copy before you, sir, of Plaintiff's
2 Exhibit 3500?

3 A. 3500, yeah. With a 1 at the end?

4 Q. Yes. That's because that's page 1 that you're looking
5 at.

6 This is the budget, for example in 2001, the year your
7 company went to market with the DePuy Pinnacle metal-on-metal
8 hip implant, correct?

9 A. Correct.

10 Q. If you will look on page 745, if you're looking at the
11 numbers in the lower right-hand corner down here, 745 are the
12 last three digits. Do you follow what I mean?

13 And tell me when you're there.

14 A. Okay. I mean, I've had no chance to study this document,
15 so . . .

16 Q. I'm not going to ask you anything that's rocket science.
17 You're going to be able to grab it immediately.

18 Tell me when you're there.

19 A. I'm there.

20 Q. All right. You've got the set-out for adjustments to a
21 budget. Do you see that?

22 A. I see that, yes.

23 Q. And if you continue to flip back, you'll get to 749. The
24 budget we're looking at, at this point, is R&D, new product
25 development, right? R&D targeted expense summary. Do you see

1 that?

2 A. I see that, yes.

3 Q. All right. So even within the R&D expense summaries, if
4 you now go to page 749 you will see that part of that budget
5 includes travel and entertainment, doesn't it?

6 A. Yes.

7 Q. Part of that is new product development?

8 A. That's correct.

9 Q. Y'all were spending more on travel and entertainment than
10 you were on developing your products, weren't you?

11 A. Well, I don't know what this document is telling me.

12 Without studying all of this document, I can't agree to that.

13 Q. What would you be looking for other than this that shows
14 the budget of -- Let's see if I can get it all up there at
15 once without us losing the ability to read it.

16 The budget line, we've got it for salaries. See?

17 A. I see that.

18 Q. You got it for travel and entertainment. Do you see
19 that?

20 A. I see that.

21 Q. You got it for sales meetings and conventions. That's
22 coming out of your research and development budget.

23 A. That's correct.

24 Q. Do you see that?

25 A. That's for the R&D folks to go there, yes.

1 Q. So the R&D folks can go to the sales meetings? Are these
2 real R&D folks?

3 A. Well, they're there educating.

4 Q. Okay. And then new product development, it's down there
5 as well. Do you see that?

6 A. Yeah, I see that. But I don't know what these dollars
7 are tying back to.

8 Q. Well, sir, the dollars are just right there. It's the
9 2000 budget. It's got the year-to-date that's actually been
10 incurred, the year-to-date that's been budgeted and what the
11 variance is.

12 I mean, this -- you deal with these sheets all the time,
13 don't you?

14 A. Yeah. And I would take my time to look at the sheet and
15 understand it and study it.

16 Q. All right. But if you --

17 A. Let's -- let's -- if you're --

18 Q. I'm sorry.

19 A. Go ahead, please.

20 Q. I've got a copy you're welcome to take home with you
21 overnight or to the hotel, and I'm going to have you on the
22 stand tomorrow. If you come to a different conclusion you can
23 tell us.

24 But for our purposes right now, it sure looks like y'all
25 spend more on travel and entertainment and going to the sales

1 meetings and conventions than you do on developing your new
2 products, don't you?

3 A. Absolutely not. I disagree with your statement based on
4 what I'm looking at here.

5 Q. And, sir, why?

6 A. Why?

7 Because if this is the R&D budget and salaries and wages,
8 what says here the 1.4 million, those are people who are
9 working hard to develop products.

10 Q. Are you talking about the 2001 budget when you went to
11 1.4 billion -- I mean million?

12 A. Correct. It's an increase. So we increased the budget
13 spent on people who are working in R&D developing products.

14 Q. Well, those are the same people though who are also doing
15 the traveling and entertainment and going to the sales
16 meetings. So you've got to divvy them up. You can't just
17 give them all to one column, right?

18 A. I'm sorry?

19 Q. That's all right.

20 A. Okay. So then let's keep going. Since -- I'm doing my
21 best here.

22 Then you've got outside consultants that are helping you
23 with your design and development of R&D products.

24 Q. Well, now time out. Time out. You want to be real
25 careful here. You understand we're going to look through this

1 stuff.

2 A. Okay.

3 Q. You know, these consulting and outside service people
4 that are getting paid out of the R&D budget are the doctors
5 that y'all got in trouble for paying, right?

6 MR. QUATTLEBAUM: Objection, Your Honor. There's no
7 foundation for that.

8 THE COURT: Overruled.

9 THE WITNESS: I'm sorry. Got in trouble for paying?

10 BY MR. LANIER:

11 Q. Yeah. You're familiar with the deferred prosecution
12 agreement with Chris Christy? Governor Christy. At the same
13 time Prosecutor Chris Christy.

14 MR. QUATTLEBAUM: Objection, Your Honor. We object
15 to any discussion of the deferred prosecution agreement. We
16 set that out in detail in the court in writing. We renew all
17 those objections at this time.

18 THE COURT: I remember all those, and I overrule all
19 those.

20 BY MR. LANIER:

21 Q. These are the doctors y'all got in trouble for paying
22 under the anti-kickback allegations that were lodged against
23 you, right?

24 MR. QUATTLEBAUM: And I object, Your Honor, to the
25 lack of foundation. They didn't get in trouble.

1 THE COURT: I'm sorry?

2 What was the last word?

3 MR. QUATTLEBAUM: They didn't get in trouble.

4 THE COURT: Overruled.

5 THE WITNESS: Yes, we signed a deferred prosecution
6 agreement with the U.S. Attorney.

7 BY MR. LANIER:

8 Q. And paid how many millions of dollars?

9 A. I don't recall the number.

10 Q. 80 something million dollars?

11 A. You're probably in the ballpark.

12 Q. And agreed to change the way you did business?

13 A. The orthopedic industry --

14 MR. LANIER: Objection, nonresponsive.

15 BY MR. LANIER:

16 Q. And you agreed to change the way you would do business?

17 A. We agreed to change, further enhance how we worked with
18 surgeons, along with the rest of the orthopedic community.

19 Q. And you personally went back and had to go through some
20 of the files and decide whether or not doctors had done enough
21 work to justify the money y'all had paid 'em. That was your
22 personal job in part, wasn't it?

23 A. We had a number of people who went through and went back
24 and looked at all payments to surgeons. And we found some
25 that we had underpaid, yes.

1 Q. Some that what had you?

2 A. Had underpaid.

3 Q. You found some you overpaid and couldn't pay anymore,
4 didn't you?

5 A. That's correct.

6 Q. That's what I was asking, sir. There were doctors that
7 y'all were not supposed to be paying legally that you quit
8 paying once you got in trouble, right?

9 MR. QUATTLEBAUM: Objection --

10 THE WITNESS: I don't believe that.

11 MR. QUATTLEBAUM: Excuse me, Your Honor.

12 I object. I would like a continuing objection first of
13 all on DPA issues; and, secondly, there's a lack of foundation
14 for Mr. Lanier's questions.

15 THE COURT: Overruled.

16 MR. QUATTLEBAUM: May I have the continuing
17 objection so I don't have to stand up over and over, judge, on
18 that point?

19 THE COURT: On that -- not on the second but on the
20 first part, yes.

21 MR. QUATTLEBAUM: Thank you.

22 THE COURT: Yes, sir.

23 BY MR. LANIER:

24 Q. All right. Let's go back to this sheet, sir.

25 The jury will get to go back look at this budget line on

1 doctor's later and whether or not that's part of sales or
2 whether or not that's part of new product development, but
3 you've got a specific budget line for new product development.
4 Don't you?

5 A. That's what it says there, but --

6 Q. And you've got a specific --

7 A. What I would say --

8 Q. Excuse me, sir.

9 Please, I've got limited time. I've got to finish in
10 four weeks. If you will hold on to my questions he'll get to
11 come after me and ask me anything he wants. Okay?

12 Do you follow what I mean?

13 A. I'll do my very best to answer the questions that you
14 pose --

15 Q. Thank you.

16 A. -- as thoroughly as I can, yes.

17 Q. Okay. Thank you.

18 You've got a line for new product development. And it's
19 189 -- what is that, thousand, 1.89 million? You got any
20 clues?

21 I think this is in thousands, isn't it?

22 A. Like I said, I've not looked at the document but I would
23 expect it's in thousands, yes.

24 Q. All right. And then if you just compare that line for
25 new product development to travel and entertainment, we'll

1 I leave out sales meetings, you're still spending more on the
2 bottom line for travel and entertainment than you are new
3 product development, aren't you?

4 A. I completely disagree with your statement.

5 Q. All right. Let's look at it again from this light.

6 Would you agree with me that key studies being done by
7 your company, these studies the jury's heard about, are really
8 just marketing studies?

9 A. I would dis-- pardon me. I would disagree with you.

10 Q. The studies were developed and put in place by marketing
11 people, weren't they?

12 A. I disagree with that.

13 Q. All right. I'm going to put a note on it and we'll look
14 at this in a little bit as well. A.E. disagrees.

15 Next.

16 The doctors and the orthopedists that y'all hired, these
17 consultants, they were working in marketing and sales, weren't
18 they?

19 A. I disagree with that.

20 Q. Dr. Thomas Schmalzried, remember him?

21 A. I do.

22 Q. You spent a lot of time with him, haven't you?

23 A. I've spent time with him, yes.

24 Q. Dr. Tom Schmalzried.

25 And the jury is going to get to hear him. Either he will

1 come live or we'll have to play a video or something if we
2 can't get him to come here. He lives in California, right?

3 A. Correct.

4 Q. He's someone y'all paid, what, 24 million dollars to?
5 He's the 24 million dollar man?

6 A. Yeah. We compensated him for his scientific
7 contributions.

8 Q. Uh-ha. Well, those scientific contributions included
9 attending your sales meeting where he stood up as a
10 cheerleader and delivered the sales pitch that the sales force
11 needed to go out and sell more of these products, right?

12 A. I would say he was at our sales meeting. I don't think I
13 would call him a cheerleader.

14 Q. Have you seen his presentation? It's on video.

15 A. I haven't seen it in a long time.

16 Q. Where he talks about, hey, you've sold a billion dollars,
17 let's sell a billion more?

18 A. I recall that, yes.

19 Q. Where he did his PowerPoint about big balls and small
20 liners, and he had all the lewd slides in it?

21 MR. QUATTLEBAUM: Objection, Your Honor.

22 THE WITNESS: That I don't recall.

23 MR. QUATTLEBAUM: Excuse me, Your Honor.

24 I object to that lack of foundation. It's grossly
25 inaccurate. He did not give that presentation at a sales

1 meeting.

2 THE COURT: Overruled.

3 MR. LANIER: He may have given it at another meeting
4 instead of the sales meeting.

5 BY MR. LANIER:

6 Q. But you've seen that presentation of his, haven't you?

7 A. Not that I recall, no.

8 Q. On behalf of DePuy?

9 A. Not that I recall.

10 Q. And he's not the only doctor or orthopedist that y'all
11 were paying to go around the country trying to convince people
12 to use your metal-on-metal, is he?

13 A. We had surgeons who were providing professional education
14 and dialogue around many things, including metal-on-metal,
15 that's correct.

16 Q. You were paying these folks, a lot of them, a cut of what
17 they sold, a percentage?

18 A. No. They received -- many of them received a royalty for
19 the intellectual property that they contribute, the science.

20 Q. Well, let's break that apart.

21 A royalty is a cut. That's a fancy word for a "cut."
22 Right?

23 A. No. No.

24 Q. For every --

25 A. No. No. I do not -- I disagree with that. I disagree

1 with how you've characterized it, a "cut."

2 Q. Time out. Time out. Let me get it out.

3 A. No.

4 Q. They would get paid a percentage of sales, wouldn't they?

5 A. They are paid a royalty based on the intellectual
6 property, the science that they contribute to the development
7 of a product.

8 Q. Sir, I -- the jury is entitled to the truth here.

9 The royalty was a percentage of money from products sold.
10 That's what you're calling a royalty, isn't it?

11 A. The royalty is compensation for their intellectual
12 property --

13 Q. I'm not asking what it's for. I'm asking what the
14 royalty is.

15 The royalty is a percentage, or cut, of money from the
16 products sold, right?

17 A. The agreement is that they receive a percentage of --
18 yes, dollars from the product sold. I dispute the phrase of a
19 "cut." It's a royalty. And it's a royalty based on their
20 contribution.

21 Q. Well, hold on.

22 Are you insinuating that Dr. Schmalzried is on the patent
23 or was an inventor of the Ultamet metal liner?

24 A. Dr. Schmalzried was a participant in the development of
25 the Ultamet liner.

1 Q. Oh -- went to ten or 11 different meetings y'all flew him
2 into and paid him to attend, right?

3 A. I don't know if we paid him to attend or not.

4 Q. Yeah. He had a consulting agreement where y'all would
5 pay him to come to these meetings and tell y'all, yeah, I
6 think I would like that or no I don't think I would like that.

7 Do you remember?

8 A. I disagree with how you've characterized it.

9 Q. All right. We'll look at those in a little more detail
10 in a minute.

11 And, of course, we have the distributors. The
12 distributors, they're not science people, they're marketing
13 salespeople, like what you were at one point in time, right?

14 A. Well, the distributors provide a logistic function.

15 Q. That wasn't my question. They're marketing and sales,
16 aren't they?

17 A. That's among -- that's among the things they do, yes.

18 Q. All right.

19 A. That's not all they do. That's among the things they do.

20 Q. All right.

21 Next subject.

22 Because you don't have a science background I'm figuring
23 I need to ask these questions of someone else, but also in
24 opening I heard what I called bizarre science.

25 Are you familiar with the phrase "bizarre science"?

1 A. I am not.

2 Q. Okay. Do you know anything about the ida that just
3 because you can take some chromium in your mouth in your
4 Centrum Silver vitamins for those who take them that that's
5 very different than the cobalt and chromium that comes off in
6 one of these implants in someone's muscle tissue?

7 Are you the right guy for me to ask those questions?

8 A. I -- I am not.

9 Q. Okay. I'll leave that alone.

10 The idea that ions is how the body's handling metal
11 debris as opposed to being a tremendous problem, are you the
12 right guy for me to ask those questions?

13 A. I am not.

14 Q. The idea that metal debris gets excreted from the body;
15 whereas, plastic debris stays in the body, are you the right
16 guy for me to ask those questions?

17 A. Not in any detail, other than I agree with that
18 statement.

19 Q. Wait a minute.

20 You are actually going to contend to this jury that metal
21 debris gets excreted out of the body and none of it stays in
22 the bodies?

23 A. Ions do, yes.

24 Q. Ions get excreted out -- there's a difference between
25 debris and ions, isn't there?

1 A. I believe you said -- maybe I misheard you. I thought
2 you said "ions."

3 Q. No, sir. Ms. Pam, typing this up minute by minute.

4 I said the idea that metal gets excreted from the body;
5 whereas, plastic debris stays in the body. You said I agree
6 with that statement?

7 A. I sorry. I misheard you --

8 Q. That's fair.

9 A. -- I heard ions.

10 Q. Thank you for clarifying on the record.

11 Because you know, even not being a science guy, that when
12 the metal ball was rubbing against the metal liner in these
13 plaintiffs and others that are out there in the world, that
14 there's debris, real small little pieces of metal that come
15 off, right?

16 A. There's the potential for metal debris, yes.

17 Q. No, not the potential for. You know that there's metal
18 debris that comes off, right?

19 A. There's the potential for it. There's the potential for
20 wear debris in all articulations.

21 Q. I wasn't asking about all right now. I want to stay on
22 metal-on-metal.

23 But there's the difference between saying there's the
24 potential and that as a matter of fact it happens. It happens
25 with each step that you take.

1 You know that to be true, don't you?

2 A. There's the potential for that to happen, yes.

3 Q. No, it does happen. It's not potential. It does, based
4 upon the work you're familiar with, right?

5 A. I think it's a potential, yes.

6 Q. Do you understand the difference between potential --
7 I've got potential to go on to a basketball court and throw
8 the ball from mid-court and make a basket. There is that
9 potential. Do you understand what I mean?

10 THE COURT: Not much of one.

11 (Laughter.)

12 THE WITNESS: Thank you, Your Honor.

13 MR. QUATTLEBAUM: I was inclined to object, judge,
14 but then I thought better of it.

15 MR. LANIER: Which makes my point.

16 BY MR. LANIER:

17 Q. A very slim potential, but the potential is there, right?

18 A. Potential, yes.

19 Q. There's a difference between saying there's the potential
20 to make that shot and saying, oh, yeah, Lanier's going to make
21 it. Those are two different statements, aren't they?

22 A. Yes.

23 Q. Okay. I'm not asking you is there the potential for
24 debris from metal-on-metal. I'm not asking about is there
25 potential.

1 I'm saying you know for a fact in the Pinnacle
2 metal-on-metal hips when there is movement in the ordinary
3 person there is going to be debris, metal debris.

4 A. The potential for metal debris, that's correct.

5 Q. Well, you just changed and went "potential" on me again.
6 Why do you keep putting that word in there?

7 A. Because I believe it's a potential.

8 Q. You don't think it happens all the time?

9 A. I don't think it does.

10 Q. So when the booklets that you've put out say that tool --
11 that this piece is self-polishing -- you're familiar with
12 those statements in your brochures, right?

13 A. Yes.

14 Q. All right. It's self-polishing. And by that you mean
15 that scratches get buffed and polished out, right?

16 A. Correct.

17 Q. Well, how does the scratch get polished out if there's
18 nothing rubbing putting off debris?

19 A. I agree.

20 Q. I mean, it doesn't take rocket science to figure out if
21 -- I'll exaggerate the drawing, and I know we've got jurors
22 that draw and I'm not a drawer and I apologize now. But if
23 you've got a crack in the ball, I just cut the ball in half so
24 we can see that crack, and I exaggerate it -- do you follow
25 me?

1 A. Yes.

2 Q. Do you see what I've done?

3 The only way you're going to polish that crack out is by
4 rubbing off some of the metal, right?

5 A. Correct.

6 Q. And when you rub off the metal that's called "debris,"
7 isn't it?

8 A. I agree.

9 Q. And the debris that comes off from these implants is so
10 small it's called nanometer debris, right?

11 Nanometer size, correct?

12 A. I believe that's correct.

13 Q. And "nanometer" means it's so stinking small you -- you
14 can't even see it under the microscope, right?

15 A. That I don't know.

16 Q. All right. We'll save that for someone else.

17 But that's the debris -- and -- and at some point do you
18 want me to ask you these questions about whether or not
19 Mr. Sarver's statement is true that you urinate these things
20 out?

21 You know for a fact you don't urinate out the debris, do
22 you?

23 A. I -- no, I don't believe you do.

24 Q. Okay. Thank you.

25 And that's the truth, isn't it?

1 Next subject.

2 I'm going to hold this subject until after the afternoon
3 break and move to a different one.

4 I want to talk to you about innovation. Okay?

5 A. Okay.

6 Q. Now, Mr. Sarver told the jury that just because a product
7 is innovated -- the innovation takes place doesn't make the
8 earlier product defective.

9 Does that ring a bell with you?

10 A. So could you just read me exactly what he said?

11 Q. I'll do you better.

12 I think it's slide 32, if I was counting right.

13 It's the slide that had the gramophone and the big cell
14 phone on it.

15 MR. LANIER: If we could find that slide from the
16 defendants, please, and put it up.

17 Thank you very much.

18 BY MR. LANIER:

19 Q. This is the slide that Mr. Sarver was using.

20 Do you see it?

21 A. I do.

22 Q. And Mr. Sarver told the jury just because a new product
23 comes out and there's innovation doesn't mean the old product
24 was defective.

25 Do you follow what I'm saying -- or what he was saying?

1 A. I don't know what he said, so I'll -- I guess I'll
2 believe you.

3 Q. Well, the point that I want to make, sir, is that this
4 isn't a situation of someone coming up with a -- the
5 metal-on-metal was never a -- a new cell phone or something?
6 Do you follow what I mean?

7 A. I don't.

8 MR. LANIER: All right. Let's go back to the ELMO,
9 please.

10 BY MR. LANIER:

11 Q. Metal-on-metal had been around for a long time. Been
12 around in the '60s and in the '70s, right?

13 A. That's correct.

14 Q. And Mr. Sarver showed the jury the McKee-Farrar
15 metal-on-metal implant, right?

16 A. Okay.

17 Q. And then the jury was told a number of different things
18 about this. And I'd like to go back and just make sure that
19 we're on the same page as you and the company.

20 The company knew that the metal-on-metal in the '60s and
21 '70s had suffered dismal failures, right?

22 A. I don't know if I would classify it like that.

23 Q. Well, the company did an analysis -- you know who Graham
24 Isaac is, don't you?

25 A. I do, yes.

1 MR. LANIER: Your Honor, I would like to approach
2 the witness, please.

3 THE COURT: That will be fine.

4 BY MR. LANIER:

5 Q. I want to hand you Plaintiff's Exhibit Number 1. I
6 showed this to the jury in my opening statement.

7 This is the End Game memo done by Graham Isaac who was
8 the development manager of hips.

9 Do you see that?

10 A. Yeah. I don't know it's a memo. I think it's a document
11 he created for himself, but --

12 Q. Okay. "Document," "memo," I mean, do y'all have
13 classifications of those things that I need to be attentive
14 to? Is there a special buzzword for at the company?

15 A. No. But I think sometimes people create a document
16 drafting it for themselves for their own reading and for --
17 you know, to organize their, you know, their own thinking
18 that's not widely distributed, I guess.

19 Q. Do -- do you have any reason to believe that this was
20 drafted just for his own personal review as opposed to anyone
21 else in the company?

22 A. In a discussion with Graham I believe he created this for
23 his own thinking.

24 Q. And so he put Graham Isaac, Ph.D., just in case he forgot
25 who he was?

1 A. I'm -- just my discussion with Graham.

2 Q. And in case he forgot his job title he wrote down
3 "development manager for hips"?

4 And he titled this "End Game, the failure of total hip
5 replacement" as just a personal, gee, I'm bored today, what
6 should I do with my time?

7 Is that really what you want us to believe?

8 A. That's what Graham told me, that this is a document he
9 put together for himself.

10 Q. Um.

11 Um.

12 So he put together a document for himself asking "What
13 causes failure?" And then he starts walking through the
14 different things that can cause failure.

15 Right?

16 Do you see this?

17 A. Yes.

18 Q. Then he says -- and he's talking about here -- this whole
19 section is poly wear or plastic wear, the wearing of plastic,
20 right?

21 That's what UHMWPE stands for, Ultimate High Molecular
22 Weight Polyethylene. A kind of plastic. Right?

23 A. Yeah. Many generations ago.

24 Q. Oh, beautiful. Beautiful. Thank you for that point.
25 Let's write that down. We're going to come back to this.

1 Ultra High Molecular Weight Polyethylene plastic, many,
2 many generations ago. That's what you just said, right?

3 A. I think I said "many," but . . .

4 Q. Right. One "many." I got carried away because I got
5 excited over it.

6 We'll come back to that, okay?

7 A. Okay.

8 Q. Now, "how does wear appear?" And "what are the
9 alternatives?"

10 Now here are the alternatives he's talking about to
11 metal-on-plastic. The old conventional plastic, right?

12 I'm assuming if you talked to Graham about this memo you
13 know what this memo says?

14 A. I haven't read it. I guess I read it a couple of weeks
15 ago, but . . .

16 Q. So you talked to him to learn how it is he wrote the memo
17 and what he meant by it, but you never read the memo?

18 A. No, I said I read it a couple of weeks ago.

19 Q. Okay. And where were you when you were talking to him.
20 This guy is over in England, isn't he?

21 A. It was on a phone call.

22 Q. Okay. You were calling him because you figured I would
23 be asking you about this?

24 A. I was curious to know where -- how we came up with
25 this.

1 Q. Okay.

2 He said there are two alternatives, ceramic-on-ceramic,
3 which we know hadn't caught on much in the U.S., but
4 metal-on-metal, "both of which have identical surfaces
5 articulating against each other - which would be normally
6 considered to be bad engineering practice." Right?

7 A. I see where he's written that.

8 Q. And it's your testimony, again, that he's told you that
9 this was just something he was just writing for himself so he
10 would know that, right?

11 A. Yeah.

12 Q. By the way, he's an engineer. He actually is a science
13 guy, isn't he?

14 A. Very much so.

15 Q. Let's skip the ceramic-on-ceramic section and go to the
16 metal-on-metal.

17 "It is clear from the literature that the survivorship
18 of cobalt chrome, metal-on-metal prostheses in the past has
19 been far from satisfactory."

20 Do you see that?

21 A. I see where he's written that, yes.

22 Q. And then he looks at the McKee-Farrar prosthesis that
23 Mr. Sarver showed the jury this morning, right?

24 A. Yes.

25 Q. And he says that it's got a 27.5 percent success rate at

1 20 years, citing the August study, right?

2 A. I don't know if that's the success rate.

3 Q. It is.

4 Would you like to see the August study before I press you
5 on it?

6 Would that help you?

7 A. Sure.

8 MR. LANIER: Your Honor, may I approach the witness?

9 THE COURT: Yes.

10 MR. LANIER: Your Honor, I'm handing the witness
11 Plaintiff's demonstrative 64 which is the August study. I
12 don't think there's an objection.

13 MR. QUATTLEBAUM: No objection.

14 THE COURT: All right. Plaintiff's Exhibit 64 is
15 admitted only for demonstrative?

16 MR. LANIER: Yes, Your Honor.

17 THE COURT: Not for evidence, simply for
18 demonstrative.

19 MR. LANIER: Thank you, Judge.

20 BY MR. LANIER:

21 Q. Do you have this August paper that is being cited by
22 Mr. Graham?

23 A. I do, yes.

24 Q. And he's looking at the McKee-Farrar metal-on-metal hips
25 that were done in these two hospitals between 1965 and 1973?

1 Do you see that?

2 A. I see where that's in the paper, yes.

3 Q. And if you look at the results of this paper, you will be
4 able to see what the success ratio was. I tell you, this is
5 going to give you -- Well, go to the survivorship section.
6 You've got a table. Table 5.

7 Do you have that?

8 A. I'm sorry. I'm just reading the document.

9 Q. Can you go to table 5, please, sir?

10 A. I'm just trying to get there.

11 Q. It's on page 525 of the document.

12 And it's got the survivorship that I've got up on the
13 screen, if you find it easier to look at it there.

14 A. I don't.

15 Q. It shows you the number of prostheses removed.

16 The annual percentage removed.

17 And the cumulative percent that survive.

18 Do you see that?

19 A. I'm getting there. I'm orienting myself on the paper.

20 Q. Sir, all I'm trying to do is take the little time that
21 I've got with you to answer your question of whether or not
22 that percentage is the number surviving. It's not going to
23 take a thorough read of the paper to get to the chart and see
24 if at 20 years the 27.51 is a number for percentage surviving.

25 Do you see that?

1 A. I'm sorry. Go ahead.

2 Q. The 27.51 is the cumulative percentage surviving after 20
3 years, true?

4 A. Yes. But it doesn't say why they failed.

5 Q. So if we go back to what Mr. Isaacs wrote in the memo, or
6 whatever you want to call it, the 27.5, that's how many
7 survived at 20 years.

8 That's survival, right?

9 A. At 20 years. If you go back in the paper, it's a much
10 lower rate at years prior to that.

11 Q. You can't get higher at years prior and have the rate go
12 down. The rate is always going to climb from lower to higher,
13 right?

14 In other words, if you've got 50 percent surviving today,
15 tomorrow you can't have 75 percent surviving.

16 A. No. I -- I understand that.

17 Q. Okay. Now --

18 A. I'm saying that there is -- at 20 years seems like there
19 is a significant increase in the number. And I -- I have not
20 had a chance to --

21 Q. Sir, none of that is what I'm asking you. I'm glad to go
22 into it with you if you want to take time from them, but on my
23 time I'd like to stick to this, please.

24 The writer, the DePuy head science guy on this -- By the
25 way, that's who Graham Isaac was? He was your head science

1 guy inside DePuy on hips at this time, wasn't he?

2 A. He was among them, yes.

3 Q. Your head science guy says "It is clear from the
4 literature survivorship has been far from satisfactory." And
5 then he gives the 27.5 percent at 20 years. He did that, not
6 me. Right?

7 A. That's what he's written there.

8 Q. Yeah, I mean, that's not me saying it, I'm not trying to
9 cherry pick something. That's his writing, isn't it? Your
10 head science guy.

11 Then he gives the Stanmore prosthesis. That's also
12 metal-on-metal, isn't it?

13 A. I believe so.

14 Q. And the metal-on-metal Stanmore implant, only a little
15 over half of those are still surviving after 11 years
16 according to the Dobbs paper, right?

17 A. According to the Dobbs paper, yes.

18 Do you have a copy of that one?

19 Q. Sure. I mean, do you really need it or is this -- what
20 good does it do you for me to give you the Dobbs paper?

21 A. I'm curious.

22 MR. LANIER: All right. Your Honor, may I approach?

23 THE COURT: Yes, sir.

24 BY MR. LANIER:

25 Q. Demonstrative number 926 is the Dobbs paper.

1 A. Thank you, sir.

2 Q. Have you got it?

3 A. I do.

4 Q. "Survivorship of total hip replacements" by Dobbs. He
5 says "The results indicate that for metal-on-metal prostheses
6 the overall probability of survival was only 53 percent after
7 11 years.

8 "The average annual probability of survival,
9 irrespective of cause, was 5.5 percent. The results were
10 better for metal-on-plastic" with 88 percent after eight
11 years, just one and a half percent respectively.

12 Do you see that?

13 A. Yes, I do.

14 Q. Okay. So within the framework Mr. Graham, Dr. Graham
15 Isaacs, points out this problem and then he starts talking
16 about why it exists. Right?

17 Do you see where he says, "This poor survivorship has
18 been attributed to" --

19 A. Yes.

20 Q. -- "poor component design and poor tolerancing of the
21 femoral head and the acetabular cups."

22 Did I read that right?

23 A. You have read that correctly.

24 Q. I want to make sure we're all on the same page on this.
25 What Dr. Isaac seems to be saying to himself, based on what

1 you've heard, is that the problem historically has been
2 attributed to the idea that there is either a bad design of
3 these components or there's a poor tolerancing of the heads.
4 The head doesn't fit well in the cup. Right?

5 A. I see where he's said that.

6 Q. That leaves an opening for the company, doesn't it?

7 A. I'm sorry, opening?

8 Q. Yeah. Y'all can come up with your own product and say,
9 hey, people have conceived that there's been poor component
10 design and poor tolerancing and we designed something better
11 with good tolerancing. There's an opening there for the
12 company, isn't there?

13 A. Well, what I would say is there is -- Pardon me. I
14 wouldn't phrase it as an opening for a company or anybody.

15 I would say it is an opportunity for the orthopedic
16 community to solve a clinical problem.

17 Q. And I would agree with you there as well.

18 My point is, sir, that your company never solved that
19 problem; they just told everybody they did. Right?

20 A. I disagree with your statement.

21 Q. All right. Well, we'll get into that in a little bit.

22 He goes on to say that "Manufacturing methods have
23 improved so that we can make these components the way we think
24 they ought to be made, together with an improved cobalt-chrome
25 material, a modern stem design, a cushioned cup has led its

1 proponents to suggest metal-on-metal is the bearing surface of
2 the future."

3 Do you see that?

4 A. Yes.

5 Q. "However, simulator testing" -- That's the machines that
6 do the exact same motion over and over and over, at least back
7 then, right?

8 The simulator machines?

9 A. Yes.

10 Q. Yeah. And you're aware of the fact that lots of people
11 have tried to modify those machines so they use different
12 motions and they start and stop now, but back then it was this
13 motion over and over y'all were doing?

14 A. Yeah. I'm not an expert on what the simulators could or
15 couldn't do then --

16 Q. All right. I'll leave it aside.

17 "However, simulator testing" -- And if anybody is going
18 to know about that, it's going to be Graham Isaac, true?

19 A. Correct.

20 Q. "Simulator testing of such components" -- These are the
21 new and improved ones -- "suggest that their performance" --
22 Can you read what that says?

23 A. He says -- he says it's unpredictable.

24 Q. As ever. "Is as unpredictable as ever, working well for
25 a period of time before suffering a sudden catastrophic

1 breakdown of the bearing surface accompanied by a release of a
2 large volume of wear debris."

3 Do you see that, sir?

4 A. I see where Graham has written that, yes.

5 Q. And I'm not taking anything out of context. We're just
6 reading the document, right?

7 A. You're reading the document, yes, I agree, except that
8 this is a period of time. So this goes back to, what, 1994?

9 Q. '95, '96.

10 A. Okay. So let's say it's '95.

11 Q. Yeah. It's within five years of when you're selling the
12 Pinnacle metal-on-metal?

13 A. Yeah. And the advancements in manufacturing are
14 significant during this period of time.

15 Q. Actually, did you talk to Mr. Isaacs about that? Because
16 in his deposition I specifically explored that with him and
17 asked him to tell me about any advances.

18 Do you recall that?

19 A. I don't.

20 Q. And he said that there weren't any.

21 MR. QUATTLEBAUM: Objection, Your Honor. It's
22 argumentative and not true

23 THE COURT: Well, let's wait until we see. Sustain
24 the objection.

25 BY MR. LANIER:

1 Q. You're not familiar with what advances there were or were
2 not. You were selling stuff for Johnson & Johnson at that
3 time, weren't you?

4 A. Correct.

5 Q. Now, he then goes on -- Dr. Isaac then goes on, page 3,
6 to start talking about -- well, he just continues, actually,
7 on metal-on-metal.

8 And he talks about how the maintenance of the bearing
9 surface quality is far from certain in a clinical situation.
10 Do you see that?

11 A. I see where he's written that.

12 Q. All right. You guys have these buzz words that maybe not
13 all of us are familiar with. So I want to make sure we've got
14 this right.

15 "Clinical situation" means in people, as opposed to a
16 machine, right?

17 A. I'm assuming that's what Graham meant. I don't know.

18 Q. Well, that's the way you use the word, right?

19 A. Yes.

20 Q. Okay. And then he looks at revision surgeries, to get
21 them out of people to see what they look like. Do you see
22 that?

23 And then he says, "So even when the surfaces are
24 manufactured optimally" -- That means the best you got, right?

25 A. At the time.

1 Q. -- "there is a mechanism whereby the surface can become
2 damaged, the bearing surface break down, and large volumes of
3 wear debris produced." Do you follow me?

4 A. I see that's what Graham has written.

5 Q. And then he says it's useful to compare the different
6 materials because the effect of the wear debris is very
7 different.

8 Do you see that?

9 A. I see that.

10 Q. Cobalt-chrome produced a more florid foreign body, and
11 chronic inflammatory reaction was associated with decreased
12 ingrowth of bone compared to particles of polyethylene.

13 Do you see that?

14 A. I see that.

15 Q. Just to emphasize the point. I guess you say he's doing
16 this just to emphasize the point itself as opposed to all of
17 y'all at this time trying to decide whether or not to go
18 forward?

19 A. I'm sorry. Repeat your question.

20 Q. Yeah. Do you think he's just emphasizing this point to
21 himself or do you think maybe as we're going through this he's
22 writing it because at this very moment your company is trying
23 to determine do we do the metal-on-metal or not?

24 A. I don't think so.

25 Q. I'm going to come back to that. Let's be very clear,

1 1995 that's the very thing -- '94 even, your company is trying
2 to figure out?

3 A. I think the orthopedic community is looking at
4 alternative bearings at this point in time because --

5 Q. That wasn't my question, sir.

6 A. Okay.

7 Q. I don't care about the community right now. I'm trying
8 this case against Johnson & Johnson/DePuy with these five
9 families that had a Johnson & Johnson/DePuy hip implant. Do
10 you understand?

11 A. Yes.

12 Q. My question is very clear 1994/1995 is when your company
13 was trying to decide about whether to go forward with a
14 metal-on-metal hip or a ceramic-on-ceramic hip, true?

15 A. I believe so. I wasn't there and part of the decision as
16 I think we've established.

17 MR. LANIER: May I approach the witness?

18 THE COURT: You may.

19 BY MR. LANIER:

20 Q. I want to give you two exhibits, sir. I want to give you
21 Plaintiff's Exhibit 35, and I want to give you Plaintiff's
22 Exhibit 667. Do you have those?

23 Do you have 35 and 667 in front of you, sir?

24 A. I'm just --

25 Q. Here. We're going to look at it together, so you will

1 get a chance.

2 These are DePuy exhibits that are protected documents
3 produced subject to a protective order. Do you see that?

4 A. I see that, yes.

5 Q. We got them in this case.

6 The jury is getting to see this document that's dated
7 February 12th, 1995. Do you see that?

8 A. I do.

9 Q. And it's the alternate bearing project. Bearing, that
10 means the ball and liner, right?

11 A. Yes.

12 Q. And alternate because at the time y'all were selling a
13 metal-on-poly, metal-on-plastic. You weren't selling
14 metal-on-metal at the time, right?

15 A. Metal-on-metal was not available, correct.

16 Q. All right. So this is the very project that y'all were
17 trying to figure out. You were doing feasibility research
18 project to research and develop alternative bearings, trying
19 to figure out if you could do something about the osteolysis
20 caused by the plastic debris, right?

21 A. Yeah. We were -- I guess. I mean, I wasn't there, but
22 reading it, I would say they were investigating alternative
23 bearings.

24 Q. And your company recognized in the commentary that
25 osteolysis is the biggest issue in orthopaedics?

1 A. Yes.

2 Q. If they could reduce the polyethylene, that would be good
3 because that's the weak link.

4 "If we provide the marketplace with an alternative
5 bearing, it would provide DePuy a true differentiating factor
6 from the competition."

7 Y'all would be different, right?

8 A. I see where that's written, yes.

9 Q. "Pushing this technology into the next generation with an
10 alternative bearing material assistance will provide us an
11 opportunity to significantly increase market share."

12 Do you see that?

13 A. I do.

14 Q. "If we can beat our competition to the punch." Right?

15 A. Yes. I think at this time if a company --

16 Q. Now --

17 A. -- solves the issue with polyethylene with alternative
18 bearings, it will be differentiated, and it will result in
19 more surgeons prescribing these products.

20 Q. Sir, with all due respect I wasn't asking you for that.
21 I'm just asking you here.

22 Would you answer my question first before the speech?

23 A. What was your question?

24 Q. Yeah. I said the key for y'all to significantly increase
25 your market share according to this memo is beating the

1 competition to the punch, get your product out there, right?

2 A. Yes. That's what's written here.

3 Q. Look at this "Collaborate with internal research and
4 Leeds R&D."

5 Do you see that?

6 A. I see that, yes.

7 Q. Leeds R&D is headed up by Dr. Graham Isaacs, Ph.D.,
8 correct?

9 A. Yes.

10 Q. That's the gentleman whose writing this memo that --
11 that's called the End Game memo, correct?

12 A. Correct.

13 Q. Because what the company was doing is at that point in
14 time trying to figure out how to get to market first with a
15 new head, true?

16 A. A new head.

17 Q. A new head and liner, yeah.

18 A. With new bearings, alternative bearings.

19 Q. Right. But you knew even then that one day you might
20 have to be dealing with us lawyers, didn't you?

21 A. No, I disagree with that.

22 Q. If you will look at Plaintiff's Exhibit 667. These are
23 the meeting minutes, 1995 May.

24 This is where y'all are meeting with some surgeons that
25 you've paid to come talk to you about whether or not this

1 bearing might be a good idea.

2 Do you see that?

3 A. I'm reading them.

4 Q. You recognize a lot of those names, don't you?

5 I mean, there are some relationships here. Steve has
6 works in the company? Marketing?

7 A. Not anymore.

8 Q. He did at that time?

9 A. I believe he was in a marketing role.

10 Q. And then he had his brother, the orthopedic surgeon from
11 Colorado there. So he's paying his brother?

12 A. I'm not sure I'd qualify it that way, but --

13 Q. Well, they're brothers. You didn't know that?

14 A. Yeah. But I'm not sure. You said Steve is paying his
15 brother. Steve is not paying his brother.

16 Q. Well, Steve has got his brother involved, and
17 DePuy/Johnson & Johnson is paying him. I'm sorry. You're
18 right. Your company is paying Steve Haas's brother ultimately
19 to sell this product, right?

20 A. No.

21 Q. Sorry.

22 A. He has been asked to help design a product.

23 Q. Look at what Dr. Peters had to say at this meeting in
24 1995. It's on the second page.

25 "We need to be cautious of the legal litigation issues

1 and lawyers, et cetera . . . perception of metal debris and
2 metal-ion release. "

3 MR. QUATTLEBAUM: I don't have page 2.

4 THE COURT: Let's take a break for 15 minutes.
5 Don't talk about the case. Thank y'all.

6 THE SECURITY OFFICER: All rise.

7 (Recess taken at 3:33.)

8 (Proceedings resumed at 3:52.)

9 (Jury enters the courtroom.)

10 THE COURT: Y'all be seated.

11 Jim, is it blowing out hot or cold air?

12 Are they hot?

13 If it's hot, let's turn them off.

14 I apologize. I used to work on these air-conditioning
15 units as -- I wasn't a real knowledgeable -- I was a grunt for
16 the guy that knew what he was doing at Baylor University, so
17 that's how old those are. Baylor has since replaced them with
18 something sensible. They're still here in the federal
19 courthouse. Anyway, they're hard to regulate, hot or cold, as
20 y'all have noticed. So, anyway, I'm working on it.

21 Go ahead.

22 DIRECT EXAMINATION (Cont.)

23 BY MR. LANIER:

24 Q. Sir, I don't want to get so lost in the weeds that we
25 lose track of where we are.

1 My point is, is in 1995, '94, '95, '96, your company was
2 looking at getting into metal-on-metal hips, and even then
3 they knew that there might be some concerns about ultimate
4 litigation issues and lawyers because of the perception of
5 metal debris and metal ion release. We can read that in black
6 and white, can't we?

7 A. I see where that's written, yes.

8 Q. And so within that time frame that your company is
9 checking with the -- the -- the fellow Graham Isaac who heads
10 the project up, he's the head over at Leeds, right?

11 A. Yes.

12 Q. Okay. Graham Isaac just happens to be writing this memo
13 that you think he was writing to himself, and he talks about
14 ". . . the only combination of materials which is likely to
15 give rise to toxic levels of metal under clinical conditions
16 is cobalt chrome articulating against itself."

17 Do you see that?

18 A. I just want to make sure I get the paper.

19 Q. This is the End Game memo, page 3.

20 A. Just reorienting. I apologize.

21 Q. That's okay.

22 A. Okay. Okay. I follow you.

23 Q. The only combination of materials which is likely to give
24 rise to toxic levels. You understand toxic means it kills
25 cells, right?

1 A. Yes.

2 Q. "-- of metal under clinical conditions" we mean -- we
3 know from that that means in the person, right?

4 A. Yes.

5 Q. "...is cobalt chrome articulating" -- that means
6 moving, doesn't it?

7 A. Yes.

8 Q. "... against itself."

9 The inside of the DePuy Pinnacle metal cup it's made of
10 cobalt chrome, isn't it?

11 A. Yeah, the Ultamet metal insert is cobalt chrome, correct.

12 Q. The Pinnacle metal-on-metal ball is made of cobalt
13 chrome, isn't it?

14 A. That is correct.

15 Q. The Pinnacle metal ball moving or articulating in the
16 Pinnacle metal cup is cobalt chrome articulating against
17 itself, isn't it?

18 A. It is, yes.

19 Q. Which your company knew, or its head science guy new, was
20 the only combination of materials likely to give rise to toxic
21 levels of metal. Right?

22 A. Based on one study from -- I don't know if it's professor
23 or Dr. Ray.

24 Q. I don't know if it's based on one or not. You don't
25 either. We don't know how many he looked at before he did

1 this memo to himself, do we?

2 A. No.

3 Q. We would assume he's a good scientist, wouldn't we?

4 A. Yes. Excellent scientist.

5 Q. We would assume that he can research and pick out the
6 best of the articles, can't we?

7 A. Yes.

8 Q. We can assume that he would have done his homework,
9 right?

10 Can't we?

11 A. Yes, depending --

12 Q. He doesn't put in here what Mr. Sarver said in opening,
13 oh, cobalt and chrome is just part of our vitamins and we need
14 to take it and these are going to be healthy. That isn't what
15 he says, is it?

16 A. I don't know what Mr. Sarver said. I don't know if
17 you've directly quoted him or not.

18 Q. So he says, "Therefore while cobalt chrome -- that's
19 CoCr, cobalt chrome, correct?

20 A. Correct.

21 Q. "While cobalt chrome may be manufactured optimally --"
22 made the best we can, right?

23 A. Way back 22 years ago, yes.

24 Q. Sir, y'all were selling them five years after this.

25 A. Yes.

1 Q. You know your patent for the Ultamet metal liner, your
2 patent, at least one of them, was already a year old at this
3 point?

4 A. Yes, but I don't believe the patent was for the
5 articulating surface, was it?

6 Q. Yes, sir, it was.

7 A. Okay.

8 Q. "There's no guarantee this quality can be maintained and
9 if the surfaces do break down the debris produced has been
10 shown to be more harmful than plastic, polyethylene," right?

11 A. I see where Graham has written that, yes.

12 Q. And then he says, "What is the solution"?

13 Well, "The more appropriate question is what is the
14 problem?"

15 Maybe the problem is not as big as you-all thought it
16 was.

17 Do you see this?

18 Do you see the section where I am?

19 A. I do, yes.

20 Q. He says, Consider the long-term results with
21 metal-on-plastic, and then he's got some here, doesn't he?
22 He's got, what, six studies he cites, right?

23 A. He does, yes.

24 Q. Let's look at the first four. The first four all talk
25 about how many of them have survived after 20 years. Right?

1 A. Yes.

2 Q. And this is metal-on-plastic, or poly, right?

3 A. It is.

4 Q. And he's already told us on the other page his two
5 studies for metal-on-metal, hasn't he?

6 He's already given those, hasn't he?

7 A. Yes. He's cited those.

8 Q. All right. One of the ones he cited on metal-on-metal
9 was the August study, and it was a 20-year study, wasn't it?

10 A. I believe it was in that range, yes.

11 Q. And the survivorship of metal-on-metal as opposed to
12 metal-on-poly was what?

13 We'll put metal-on-metal on the side.

14 What was the survivorship, sir?

15 A. I don't recall.

16 Q. Can you look?

17 You've got it there. And I want the jury to stay on this
18 page. Have you got it?

19 A. I'm looking for it.

20 Q. Hang on. I found it. 27.5 percent. Is that right?

21 A. Yes.

22 Q. Now, Mr. Sarver put up in his opening this graph that
23 says, oh, after 20 years it turns out that metal-on-poly is
24 worse than metal-on-metal, right? Not according to the
25 studies of your top scientist, right?

1 A. These aren't his studies.

2 Q. They're the studies he chose to put in his paper.

3 A. They're the studies he chose to put in his paper.

4 Q. I mean, he's got all the literature at his disposal.

5 These are the ones he chose, isn't it?

6 A. Those are the ones he chose, yes.

7 Q. And the difference between metal-on-metal and
8 metal-on-poly is the difference between night and day, isn't
9 it?

10 A. I'm not sure how you characterize it as night and day.
11 Yes, they're different.

12 Q. And then he shows some metal-on-poly that lasted for 10
13 and 11 years. Do you see that?

14 A. I see that, yes.

15 Q. What were his metal-on-metal -- I mean metal-on-metal
16 results at 11 years?

17 A. Don't know.

18 Q. 53 percent, weren't they?

19 The Dobbs paper you wanted to look at. Remember?

20 A. Yeah.

21 Q. 53 percent.

22 Again, at 10 or 11 years advantage metal-on-poly. True?

23 A. Yeah. I don't know if you can compare all of these
24 statistics. I have not read all the papers, but --

25 Q. I'm talking about what he did, your lead scientist.

1 You're not going to trump his science, are you?

2 You're a business guy, you're a sales guy. Right?

3 A. But I'd want to -- if I was debating with him and wanted
4 to review with him, I would want to read the papers.

5 Q. Well, when you talked to him a couple of weeks ago, did
6 you not say did you do your homework well?

7 A. No.

8 Q. Did you challenge him and say you wanted to take him on
9 on the science?

10 A. No.

11 Q. You read this before you talked to him, did it occur to
12 you that maybe you ought to probe him on those things before
13 you testified to the jury?

14 A. No, that's not what I discussed with him.

15 Q. He goes on to say on plastic "While the problem of wear
16 is present, the results are still excellent when compared with
17 the results for metal-on-metal given above."

18 Do you see that?

19 A. I see where he's written that, yes.

20 Q. "When dealing with patients, a modification to something
21 that's very successful would appear to be a safer and more
22 appropriate solution."

23 Do you see that?

24 A. I see where he's written that, yes.

25 Q. In other words, if you could modify the plastic that's

1 been very successful, that would appear to be safer and that
2 would appear to be more appropriate, what he records, isn't
3 it?

4 A. Assuming you can modify the plastic.

5 Q. Oh, we know we could. Y'all modified your plastic. Two
6 years later you came out with Marathon. Three years later.
7 Didn't you?

8 A. Yes, we did.

9 Q. And Marathon is what Coach K had, your big poster boy for
10 these, right?

11 Y'all put -- his doctors put Marathon poly liners in him.
12 They didn't put metal-on-metal, did they?

13 A. Metal-on-metal wasn't available.

14 Q. It was for a second hip in 2002.

15 A. I don't recall.

16 Q. It was available in 2002, wasn't it?

17 A. Metal-on-metal?

18 Q. Yeah.

19 A. Yes.

20 Q. You didn't know he had his second hip done in 2002 and
21 still went metal-on-poly?

22 A. I don't recall when he had his -- either one of his hips
23 done.

24 Q. Didn't stop y'all from using him for your metal-on-metal
25 ads, though, did it?

1 A. Used him for our overall promotion on hips, yes.

2 Q. "Conclusion. The alternatives have either mixed results,
3 ceramic-on-ceramic, or are building upon past failures,
4 metal-on-metal, with partial solutions in the hope of future
5 success.

6 "Which option would you favor?"

7 Do you see that?

8 A. Yeah, I see where he's written that, yes.

9 Q. And do you think he was writing that to himself, too,
10 which option would you favor? He just wrote it that way
11 instead of which option would I favor?

12 A. I don't know.

13 Q. Just reading this don't you get a feel that he was
14 probably writing this for you guys that were saying we want to
15 talk to Leeds and see what they had, see what they thought?

16 A. I can't speculate based on one sentence.

17 Q. Well, but it's not just one sentence. I mean the whole
18 thing. It sort of reads like he was writing it for someone
19 else.

20 He even puts at the end a bibliography with all of his
21 citations so that y'all can look up all of the papers, doesn't
22 he? His references?

23 A. Yeah. He's provided a thorough review of his references.
24 That's great.

25 Q. Okay. This is, so we're clear, a time period when y'all

1 were chasing market share, weren't you?

2 A. Chasing market share?

3 Q. Yes, sir.

4 MR. LANIER: May I approach, Your Honor?

5 THE COURT: Yes.

6 BY MR. LANIER:

7 Q. I'm going to give you Plaintiff's Exhibit 279, make sure
8 we're still on the same page.

9 Do you have Plaintiff's Exhibit 279 in front of you?

10 A. Yes, I believe I do.

11 Q. Now, this predates y'all looking to Graham Isaacs for his
12 information. It's dated October 10, 1994. That's before
13 y'all went to Graham Isaac. Do you see that?

14 A. I see the date, yes.

15 Q. Because y'all went to Graham Isaac, that was Exhibit
16 Number 35, where you said February of '95 will collaborate
17 with internal research and Leeds R&D. Remember?

18 A. I see that, yes.

19 Q. So before y'all ever decided to go to Leeds and talk to
20 your top scientist you had a project called metal-on-metal,
21 and the objective was to provide the market an alternative to
22 the parts, modular acetabular components with the plastic
23 liner, the old plastic liner. Do you see that?

24 A. I do, yes.

25 Q. And the objective was to grow market share by three

1 market share points in the first three years of product
2 launch.

3 You see?

4 Do you see that?

5 A. I see where that's written, yes.

6 Q. Y'all's philosophy was to push technology into the next
7 generation.

8 A. Yes. Advance innovation.

9 Q. Thinking it would -- no, it's advance sales.

10 You didn't have answers according to Graham Isaac, right?
11 Do you follow what I'm saying?

12 Sir, it's a wonderful thing to do advances, but you need
13 to do them responsibly, right?

14 A. Yes. I agree.

15 Q. And if you don't have answers, don't pretend you got
16 answers. Fair?

17 A. No, I think you pursue the answers, yes.

18 Q. But ultimately what y'all did is y'all told the world
19 that you did have answers, didn't you?

20 A. Yes.

21 Q. And, in fact, you did not have those answers.

22 A. I disagree.

23 Q. Well, let's go back for a moment.

24 I asked you before the break, we were talking about
25 this -- this is the first exhibit you and I made together

1 where we were looking at the J&J DePuy excuses versus the
2 truth -- or themes versus the truth.

3 Do you remember this?

4 A. Themes versus truth?

5 Q. Yes. And I talked to you about re-calling the ASR in
6 August of 2010, but you just kept pushing people to Pinnacle
7 metal-on-metal like Ms. Aoki?

8 Do you remember that?

9 Because she had her's then, September.

10 A. You said pushing, yes.

11 Q. And you said, oh, no, no, Pinnacle metal-on-metal was
12 performing very well.

13 And I wrote that down, and I said are you serious.

14 A. Yes.

15 Q. Do you remember?

16 Sir, during the break I went to three of your top doctors
17 that still work for DePuy that were paid millions and millions
18 of dollars, tens of millions of dollars on this product -- you
19 understand?

20 Dr. Schmalzried, you know him?

21 A. I do.

22 Q. We talked about him briefly.

23 In his deposition he was asked:

24 "Q. So the last metal-on-metal total hip replacement you did
25 would have been when?

1 "A. March of 2010. "

2 He quit, didn't he?

3 A. That's what he says there, yes.

4 Q. Dr. Barrett, William Barrett, who put in the very first
5 Pinnacle metal-on-metal hip or Pinnacle hip.

6 "Q. Did there come a time when you stopped using the cobalt
7 chromium metal-on-metal liners?

8 "A. There was.

9 "Q. And when was that?

10 A. The summer of 2010. "

11 He quit, didn't he?

12 A. And he mentioned there are several reasons we wouldn't
13 keep -- should we keep going? I don't know what his reasons
14 were.

15 Q. My point is he quit, didn't he?

16 A. Yeah, but let's continue on. Let's hear whatever his
17 reasons. If you're going to -- if you're going to say he
18 quit, let's find out why he quit.

19 Q. Okay. We will. Give me time.

20 Then you remember Dr. Fehring, don't you?

21 A. Yes.

22 Q. Dr. Fehring is the one who's given the presentations like
23 Exhibit Number 10, metal-on-metal total hip arthroplasty, how
24 did we get here.

25 That's Thomas Fehring. That's Dr. Fehring, isn't it?

1 A. Yes.

2 Q. He's the one who tells everybody in his disclosure --

3 MR. QUATTLEBAUM: Your Honor, I would object to the
4 use of this document. This is Dr. Fehring's document.
5 Dr. Fehring is not an agent of DePuy. We had this discussion
6 earlier.

7 THE COURT: And I do remember that. And I overrule
8 your objection for all the reasons you previously made to me,
9 and I do remember those.

10 BY MR. LANIER:

11 Q. I mean, Dr. Fehring even discloses, as he's saying this,
12 he's getting royalties from DePuy and J&J, and he's a J&J
13 consultant and he gets research support from y'all. Y'all pay
14 his research, right?

15 A. He gets some support, yes.

16 Q. And he's the one who said hip surgeons were seduced into
17 using metal-on-metal by manufacturers. That would be DePuy.
18 Right?

19 A. I don't think he said -- From what I read there, it
20 doesn't say that they were seduced by manufacturers or by
21 patients or by -- I can't read under your hand -- or
22 themselves.

23 Q. Well, hip surgeons were seduced into using
24 metal-on-metal.

25 Manufacturers. You think he's saying that manufacturers

1 were also seduced into using metal-on-metal?

2 A. I don't know what he's saying. I have not seen him
3 present this paper.

4 Q. DePuy was a manufacturer of metal-on-metal and was at the
5 time, wasn't it?

6 A. Yeah, we're among them.

7 Q. And DePuy ran all the ads for metal-on-metal to patients.
8 Y'all had a big campaign on Pinnacle direct to consumers,
9 right?

10 A. It's not metal-on-metal.

11 Q. It's got a metal liner.

12 A. Yes. But it wasn't --

13 Q. Okay. And then it was DePuy who also paid the doctor's
14 community to go around and to give lectures and dinner talks
15 and -- and have surgeons invited into the operating room and
16 all the rest, right?

17 A. Sir, I have no idea if that's what Dr. Fehring is saying
18 in this paper.

19 Q. Sir, DePuy paid doctors to go around and give dinner
20 speeches for their product, their metal-on-metal product,
21 didn't they?

22 A. We paid them to educate other surgeons on metal-on-metal
23 and other bearing materials and other surgical techniques.

24 Q. Is that a yes or no?

25 A. We paid them to educate, yes.

1 Q. Sir, you called it education. This came out of a sales
2 and marketing budget. Y'all did a targeted marketing campaign
3 because you figured out how many more you could sell if you
4 had these surgeon dinners, right?

5 A. It's education.

6 Q. Okay. I thought surgeons did all of that school that
7 Mr. Sarver talked about where they're already educated, and
8 they don't need to be educated further.

9 Is it your experience y'all need to teach them things
10 they didn't know?

11 A. It's my experience that surgeons like to listen to other
12 surgeons and learn from their experience. Absolutely. That's
13 actually the foundation of their training.

14 Q. Dr. Fehring --

15 A. And they like to continue that.

16 Q. "Q. Dr. Fehring, When you said you used metal-on-metal
17 for about a year, would that be before this date, before
18 September 28th of 2010?

19 "A. Correct.

20 "Q. What year?

21 "A. Maybe 2008, 2009, I'm not sure."

22 He quit too, didn't he?

23 Didn't he?

24 A. He used it for a short period of time, yes.

25 Q. So some of your very top doctors who are making top money

1 on this, they quit using the Pinnacle metal-on-metal even
2 though you were saying it's performing very well and your
3 company was telling doctors keep putting it in there, right?
4 A. It was performing well and what we don't get to in your
5 review is why did they stop.

6 Why don't we put up why they stopped.

7 Q. Sir, we got an answer to some of this by looking at the
8 internal data within the company. Y'all kept track of
9 revision rates, didn't you?

10 A. Yeah, we monitor a number of different sources on
11 performance of product, that's correct.

12 Q. And your company knew that -- Well, we'll get to that
13 tomorrow. Let me go back to something else I want to clean up
14 before we run out of time today.

15 You and I were talking at another point about how the FDA
16 clearance process went. Do you remember that?

17 A. Yes.

18 Q. And it was when we were talking about the ASR being
19 substantially equivalent in safety and efficacy to the
20 Pinnacle. Do you remember that?

21 A. Yes, I do.

22 Q. And then I talked about how the Pinnacle was said to be
23 substantially equivalent, and that was to the Ultima, among
24 other things, right?

25 A. Yes. The Pinnacle Ultamet --

1 Q. Was equivalent to the Ultima?

2 A. -- among other things.

3 Q. And Pinnacle is called the Ultamet, m-e-t, but there's an
4 earlier device that goes before it that was called the Ultima.
5 Right?

6 A. That's correct.

7 Q. And that's where y'all got in through the FDA without
8 testing the product under PMA requirements --

9 A. Well, hold on. The FDA --

10 Q. Yes, sir.

11 A. -- guided us to a 510(k).

12 Q. Time out. Time out. Time out. No, sir.

13 You're familiar with New England Journal of Medicine
14 article writing up this fiasco, aren't you?

15 MR. LANIER: May I approach, Your Honor?

16 THE COURT: Yes.

17 BY MR. LANIER:

18 Q. Are you familiar with the New England Journal of Medicine
19 writing up this fiasco?

20 A. I am not.

21 Q. One of the preeminent medical journals in the world,
22 isn't it?

23 A. Certainly among them.

24 Q. The New England Journal of Medicine, January the 10th,
25 2013, "The 510(k) ancestry of a metal-on-metal hip implant."

1 510(k), that's the FDA rule that y'all got this under,
2 right?

3 A. In working with the FDA --

4 MR. LANIER: Objection, nonresponsive.

5 THE COURT: Sustained.

6 BY MR. LANIER:

7 Q. The 510(k) is the FDA rule y'all got permission to sell
8 the product under, right?

9 It's a yes or no.

10 A. It's a yes.

11 Q. Okay. Thank you.

12 "Q. "Many medical devices that pose great safety risks to
13 Americans, including metal-on-metal hip implants, concurrently
14 enter the U.S. market through an FDA investigator pathway that
15 is not intended for evaluating safety and effectiveness. This
16 pathway, called the 510(k) process, instead involves
17 evaluation of substantial equivalence to previously cleared
18 devices, many of which have never been assessed for safety and
19 effectiveness and some of which are no longer in use because
20 of poor clinical performance."

21 Do you see?

22 A. I do.

23 Q. This 510(k) clearance, they call a loophole. Companies
24 who market these devices are often legally able to obtain
25 clearance without demonstrating safety and effectiveness by

1 claiming substantial equivalence to earlier predicate devices,
2 which themselves may have been found substantially equivalent
3 to earlier devices, and so on, all the way back.

4 Do you see that?

5 A. I see where these authors have written that, yes.

6 Q. And then, as Mr. Sarver said to the jury, the
7 peer-reviewed literature -- which is sacrosanct and important
8 and all of this. That's what the New England Journal of
9 Medicine is. It's peer-reviewed literature, isn't it?

10 This may not be its perspective, but this is a
11 peer-reviewed journal, isn't it?

12 A. Yes. I don't know if this one particular article would
13 have been peer-reviewed, but I --

14 Q. And they focus in on your ASR, which was based in part
15 ultimately on the Pinnacle Ultamet, which works its way all
16 the way back to that old McKee-Farrar that Graham Isaacs wrote
17 about, doesn't it?

18 Do you see that?

19 A. I see that.

20 Q. High rate of revision, no longer in use.

21 It's true, isn't it?

22 A. That the McKee-Farrar is not in use?

23 That's correct.

24 Q. High rate of revision, no longer in use, discontinued
25 device.

1 Not only that, but the other metal-on-metal that
2 Mr. Sarver showed this jury in opening that had that long
3 screw hole -- I mean screw end on it, the Ring hip system,
4 high rate of revision, no longer in use. Right?

5 A. Correct.

6 Q. The other metal-on-metal y'all relied upon for ASR and
7 for Ultamet, Pinnacle, Sivash hip system, high rate of
8 revision, no longer in use. Right?

9 A. And what I don't know based on this article is did we
10 rely on those. I don't know.

11 Q. Well, sir, this whole article is based on your ASR, which
12 was supposed to be substantially equivalent to the Pinnacle as
13 you chain it all the way back. Remember?

14 This is the one you re-called, sir. Remember?

15 A. No, I understand that.

16 Q. And Pinnacle metal-on-metal is the one you quit selling.
17 Remember?

18 A. Yes.

19 Q. And as you chart them back the Pinnacle metal-on-metal
20 was based on the Ultima.

21 A. Correct. Among other things. Among other things.

22 And the Ultima is the one that I said to you before the
23 break don't you remember that part of its problem is the
24 metal-on-metal debris. And you said, no, I don't remember
25 that.

1 Do you recall?

2 A. I do.

3 Q. Let me give you Plaintiff's Exhibit 1052.

4 MR. LANIER: May I approach, Your Honor?

5 THE COURT: Yes.

6 MR. LANIER: Thank you.

7 BY MR. LANIER:

8 Q. 1052 is the British equivalent of the FDA. Mr. Sarver
9 mentioned the organization in opening but not this document,
10 the MHRA.

11 MR. QUATTLEBAUM: We would renew our objection on
12 Ul t i m a.

13 THE COURT: And I do remember that objection.
14 Overrule your objection.

15 BY MR. LANIER:

16 Q. MHRA, correct, that's the British FDA?

17 A. Yes.

18 Q. And they put out an alert. And their alert was in 2007.
19 Wasn't it?

20 A. It was.

21 Q. And it was dealing with the Ul t i m a, DePuy Ul t i m a
22 metal-on-metal articulation, wasn't it?

23 A. In conjunction I guess with the TPS femoral stem, a
24 cemented femoral stem, yes.

25 Q. And if you look at the conclusions in the back, they give

1 background and investigate.

2 This was introduced by Johnson & Johnson Orthopedics, and
3 they talk about the metal-on-metal. They talk about it being
4 cobalt and chromium. They talk about their extensive
5 investigation to establish categorically why it sometimes
6 corrodes.

7 Do you see that?

8 A. I'm trying to catch up.

9 Okay.

10 Q. Do you see where it says it?

11 A. Yeah, it says the Ultima TPS, the stem, sometimes
12 corrodes. It says --

13 Q. If you look at the very next page it says, "Following the
14 investigations and retrieval analysis DePuy believes" -- This
15 is DePuy's work, not the government's, right?

16 Do you see, sir, where it says "DePuy believes"?

17 A. I do.

18 Q. This isn't the government. This is DePuy?

19 A. Yes.

20 Q. "DePuy believes that the necrosis" -- which means dead
21 tissue, right?

22 A. Yes.

23 Q. "... observed at revision is caused by patients
24 reacting to much higher levels of metallic ions than normal in
25 a metal-on-metal articulation derived principally from the

1 corroded surfaces of the stem combined with that generated
2 from normal wear of the metal-on-metal bearing. "

3 Do you see that?

4 A. Yeah, it says, as I read it, the principle issue is
5 corrosion from the stem combined with that generated from
6 normal wear of a metal-on-metal bearing.

7 Q. Normally wear of a metal-on-metal bearing itself, even by
8 your own admission, you being DePuy, was contributing to this
9 problem, wasn't it?

10 A. But -- well, what I would say is the issue is the stem.

11 Q. Wasn't my question, sir.

12 My question is by the company's -- I mean, the company is
13 going to put the best shine on this it can, isn't it?

14 A. No, I disagree with that.

15 Q. All right.

16 A. I disagree with your statement.

17 Q. By the company's own admission, the company is saying
18 some of this is coming from the corroded surfaces of the stem.
19 Some of it's coming from that generated from normal wear.
20 This isn't anything abnormal. It's normal wear generating
21 this problem, isn't it?

22 A. Yeah. As I read it, it's around the wear that's coming
23 from the corroded surface of a stem. And just -- just so you
24 understand --

25 Q. Do you ignore the "combined with" part?

1 A. Neither of these products were sold in the United
2 States.

3 Q. Actually the Ultima was. It was used in the United
4 States.

5 A. That product was never sold in the United States, sir.

6 Q. This is the one y'all said was substantially equivalent
7 for the Pinnacle.

8 A. It's a different product.

9 Q. The Ultima is different?

10 A. The Ultima sold outside of the United States and the
11 Ultima sold in the United States were different metals.

12 Q. Okay. I will fuss that with whomever I need to, if I
13 need to. I don't think that's really an issue in the case.
14 So I want to come back to my issue and not distract anything.

15 Even your company knew dead tissue was from metal ions --
16 higher levels of metal ions than normal in the
17 metal-on-metal?

18 A. Derived principally from --

19 Q. Let me finish my question. When the ion levels go up, it
20 can kill the tissue, can't it?

21 A. Yes. And in this case those can be derived principally
22 from corroded surfaces of a stem.

23 Q. Go ahead and finish. Combined with?

24 A. Combined with that generated from normal wear.

25 Q. Because it's not just -- All right.

1 A. In a product not sold in the United States.

2 Q. In the predicate product that's substantially equivalent.

3 All right?

4 A. Incorrect.

5 Q. And then the last thing I wanted to ask you is whether or
6 not Johnson & Johnson helped orchestrate the planning of how
7 to respond to this issue.

8 MR. LANIER: And, Your Honor, if I may approach.

9 THE COURT: Yes.

10 MR. LANIER: Plaintiff's Exhibit Number 65.

11 THE WITNESS: Thank you.

12 MR. LANIER: Yes, sir.

13 Your Honor, we would move Plaintiff's Exhibit Number 65
14 into evidence.

15 MR. QUATTLEBAUM: We have -- object, Your Honor.
16 This is a document I believe from Australia, deals with the
17 ASR issue in Australia. It is not relevant to this action and
18 more prejudicial than probative in all respects, and is --
19 with regard to Australia a subsequent remedial issue.

20 THE COURT: Overall your objections. Also I do
21 remember your other objections generally to ASR and I overrule
22 that.

23 MR. QUATTLEBAUM: Thank you.

24 MR. LANIER: Thank you, judge.

25 BY MR. LANIER:

1 Q. ASR XL, this was the product that your company re-called
2 in August of 2010 in the U.S. The re-calls were later in
3 different places around the world, right?

4 A. I actually believe it was a global re-call, but I wasn't
5 part of the re-call. But I believe it was a global re-call.

6 Q. You didn't know in India y'all were still selling them
7 until 2012 and the Indian government came in to shut y'all
8 down from doing it?

9 MR. QUATTLEBAUM: Object, Your Honor, lack of
10 foundation.

11 THE COURT: If he knows.

12 THE WITNESS: I'm unaware of that.

13 BY MR. LANIER:

14 Q. Okay. "ASR situation assessment."

15 Here's the second meeting on how to deal with this
16 situation. Do you see that?

17 A. I see where that's written.

18 Q. "Evaluate 4 strategic options --"

19 A. What page is this?

20 Q. This is on page 4.

21 "Evaluate 4 strategic options based on the results."

22 Do you see that?

23 A. I'm just catching up.

24 Q. Are you there?

25 A. Yes. Thank you for your time.

1 Q. Okay. Good. Option 1, "Defend: Its surgical
2 technique."

3 The surgeon put it in wrong.

4 Do you see that?

5 A. I guess I would look at it a little differently. I would
6 look at it as there is always an opportunity to train surgeons
7 on their surgical technique and if you find that there is a
8 higher revision rate there is an opportunity to train on a
9 surgical technique.

10 Q. I appreciate you taking it that way, but that's not what
11 it says.

12 It uses the word "defend," doesn't it?

13 A. That's what someone has written here --

14 Q. Excuse me, sir.

15 I'm asking you what it says. It says "defend" doesn't
16 it?

17 A. You've read that correctly.

18 Q. That's like the arguments for Ms. Aoki, that the spacing
19 was wrong from the surgery or something, the surgeon had to
20 put in a different size liner or something. Defend its
21 surgical technique. That was strategy one, wasn't it?

22 A. Well, if you can help educate surgeons on a better
23 surgical technique that's a good thing.

24 Q. Strategy -- well, it doesn't -- "Strategy 2. Defend:
25 Its patient selection."

1 There's something wrong with the patient.

2 Do you see that?

3 A. I don't think that's something wrong with the patient.

4 Q. Oh, yeah, this is someone who is hypersensitive or this
5 is someone who has got a cyst or this is someone who rides a
6 bicycle too much or this is someone -- I mean, you put it in
7 the wrong patient.

8 A. Well, there are certain select patient selection criteria
9 that may or may not be something you want to look at.
10 Absolutely.

11 Q. "Defend: It's patient selection."

12 Oh, by the way, patient criteria, do y'al put that in
13 your brochures and in your advertisements and in your
14 literature, there's patient -- what'd you call it?

15 A. No. That's not what I said.

16 Q. No, you said --

17 A. I use patient criteria --

18 Q. Yeah. There's patient selection criteria.

19 Tell me what the patient selection criteria is for the
20 Pinnacle metal-on-metal insert.

21 A. I don't know it off the top of my head.

22 Q. Would you agree with me if there's going to be patient --
23 well, let's go back.

24 Defend Number 3, global results are good.

25 Do you see that?

1 A. Yeah. I think you want to look at all your data sources
2 and determine your global results.

3 Q. So, for example, in this case when Mr. Sarver gets up to
4 the jury and says, okay, admittedly in the biggest databases
5 our metal-on-metal has failed, but, hey, it's better in some
6 other databases, look at Sweden, Sweden never used your
7 Pinnacle metal-on-metal implants, did they?

8 A. I don't know the answer to that.

9 Q. Phase out: If none of three works.

10 Then you develop soft landing strategies.

11 Do you see that?

12 A. I see where that's written, yes.

13 Q. And that's what y'all did with ASR when you tried to just
14 transfer people over to Pinnacle. And it's what you've done
15 with Pinnacle metal-on-metal as you've now agreed people ought
16 to be using poly. Right?

17 A. Well, I would characterize it much differently than
18 you've characterized it.

19 Q. All right. One last piece of clean up from earlier today
20 and then we'll see if we've got time for another subject.

21 I asked you -- we were going over the budget. I asked
22 you if maybe some of those doctors' and consultants' money
23 wasn't actually part of marketing and sales as opposed to
24 science.

25 I specifically talked to you about the 24 million dollar

1 man, Dr. Thomas Schmalzried, and whether he was in marketing
2 and sales or science.

3 Do you remember that?

4 A. Yes. And he's in science.

5 Q. And we got -- well, we're going to probe that. We got
6 into the fuss, now, over what a royalty was.

7 You will agree with me that y'all were giving a
8 royalty -- a percentage -- I was using the word cut -- of
9 money from products sold. That includes Dr. Schmalzried,
10 doesn't it?

11 A. On products that he has contributed intellectual property
12 to, that would be correct.

13 Q. Is that a yes?

14 A. Yes.

15 Q. Okay. Thank you.

16 So let's see what his contribution was.

17 First of all, at the sales meeting he went to he made a
18 presentation --

19 MR. LANIER: May I approach, Your Honor?

20 THE COURT: Yes.

21 BY MR. LANIER:

22 Q. Plaintiff's Exhibit 44. This was his presentation at the
23 sales meeting, wasn't it?

24 A. I don't know. I'd have to look through it.

25 Q. Let's look through it together.

1 The second billion, this has got that ASR that got
2 re-called, right?

3 You see it?

4 A. Yes, I do.

5 Q. This has got the Pinnacle metal-on-metal. Right?

6 Also called Ultamet. Do you see it?

7 A. I'm just trying to catch up.

8 Q. Well, it's right on the front page. It's not going to be
9 hard.

10 A. Oh, okay. Yes, I see that.

11 Q. Okay. This is that doctor. He played college
12 basketball. He's got in here, "I'm finally going to get to
13 play with Coach K."

14 That's the same year that y'all were using Coach
15 Krzyzewski to help sell the product, right?

16 A. We were using Coach K to -- for the benefits of --

17 Q. Let's be clear. You're not using Coach K for science.
18 This is marketing/sales, isn't it?

19 A. Yes.

20 Q. So when your 24 million dollar doctor is going to get to
21 play with Coach K, he's not playing with Coach K on science,
22 he's on the marketing/sales side of the equation, isn't he?

23 A. Yes.

24 Q. And you can look the it, and he calls Pinnacle the
25 billion dollar baby. And I said to you do you remember him

1 being a cheerleader about this.

2 You said I wouldn't call him a cheerleader.

3 "You can sell more." Did you ever see him yell that out
4 to the audience, "You can sell more"?

5 A. No.

6 Q. I mean, he's talking to the sales force here.

7 He's not talking to science, is he?

8 A. No. He's talking to the sales force. There's nothing
9 wrong with having him come talking to the sales force.

10 Q. "The first billion is the hardest. A billion here a
11 billion there, pretty soon it adds up to real money. Anyone
12 want to go for two?"

13 My whole point, sir, is we got into this because you said
14 oh, no, that money we were paying to doctors and orthopedists
15 was for science, not sales. I'm just saying this man who gets
16 a cut, royalty percentage, sure seems to be working on sales
17 to me, doesn't he?

18 A. Yeah. He attended a national sales meeting and talked
19 about the clinical product.

20 Q. National sales meeting, "Too much good stuff. The second
21 billion. Do you know how to do it?"

22 In here he's starting to tell them how to sell. Isn't
23 he?

24 A. Yeah, he's talking to the -- talking to the sales force.

25 Q. Okay. I will quit going through this if you will just

1 agree with me that Dr. Schmalzried is a -- is -- is out there
2 selling this product. He's part of marketing and sales.

3 Let's put him -- let's go ahead and put him where he
4 belongs. Okay?

5 Do you agree with me?

6 A. I think he's also on the science side. That was my point
7 earlier.

8 Q. Let's look at the science side. Let's look at some of
9 the speeches he's given for science.

10 MR. LANIER: Your Honor, may I approach?

11 THE COURT: Yes.

12 BY MR. LANIER:

13 Q. I give you Plaintiff's Exhibit Number 69.

14 MR. LANIER: I move Plaintiff's Exhibit 69 into
15 evidence.

16 MR. QUATTLEBAUM: This is something Dr. Schmalzried
17 did in a debate with another doctor at some meeting not on
18 behalf of DePuy or not for DePuy. Dr. Schmalzried would be
19 the person to ask about it.

20 THE COURT: Overrule your objection.

21 BY MR. LANIER:

22 Q. Do you have Exhibit 69 in front of you?

23 A. Yes, I do. Yes. Sorry. I keep forgetting how to find
24 the number.

25 Q. All right. "Big balls and thin liners: A triumph of

1 hope over reason."

2 This is your superstar doctor, isn't it?

3 Y'all have flown him around in the company jet, right?

4 A. I don't know how many times he would have used -- or
5 we've flown him around, I can't tell you.

6 Q. "Point of view: The same thing can be bad or good,
7 depending upon what you've seen."

8 It's not the first time he used this slide. He's used it
9 repeatedly, hasn't he?

10 A. I don't know the answer. And I've -- I've not seen him
11 use the slide.

12 It's quite offensive, actually.

13 Q. It is, isn't it?

14 A. Yes.

15 Q. "Identifying the issues. It's not the size. It's not
16 the material. The critical issue is the position of the cup.
17 It's not the position, it's not the material, the critical
18 issue is the size of the butt."

19 "Thank you. This presentation was supported by DePuy and
20 the Piedmont Foundation."

21 Do you know who the Piedmont Foundation is?

22 A. I do not.

23 Q. That's a foundation that Dr. Schmalzried set up by
24 himself, with his wife --

25 MR. QUATTLEBAUM: I object, Mr. Lanier is

1 testi fying. He's not even asking a question.

2 THE COURT: Overruled.

3 BY MR. LANIER:

4 Q. The Piedmont Foundation is -- tell me if this refreshes
5 your memory, the Piedmont Foundation is something that
6 Dr. Schmalzried set up to funnel money from DePuy into him and
7 his hospital and his research.

8 A. I have no idea what the Piedmont Foundation is. And, as
9 I said, I think this is an offensive document.

10 Q. Supported by DePuy?

11 A. I don't know if it was or wasn't. I haven't talked to
12 Dr. Schmalzried about this --

13 Q. The first time --

14 THE COURT: Y'all don't talk over each other.

15 MR. LANIER: I'm sorry, I didn't hear.

16 THE COURT: Say what you said.

17 THE WITNESS: You would have to talk to
18 Dr. Schmalzried about this. And, as I said, I think it was an
19 offense document.

20 BY MR. LANIER:

21 Q. Okay. Y'all paid for Dr. Schmalzried's lawyers in these
22 cases, don't you?

23 A. I don't know the answer to that.

24 MR. LANIER: Your Honor, may I approach again?

25 THE COURT: Yes.

1 BY MR. LANIER:

2 Q. Here's another one, Demonstrative Exhibit 33.

3 Do you have Exhibit 33 in front of you, sir?

4 A. Yes, I do.

5 MR. LANIER: Your Honor, it's a demonstrative
6 exhibit only at this point but I would move to show the jury
7 Demonstrative 33.

8 MR. QUATTLEBAUM: Your Honor, it's hearsay, one.

9 Two, this witness has said he has no idea about this, so
10 all of these questions are merely argumentative because the
11 lack of foundation is established by the answer.

12 THE COURT: Overruled.

13 BY MR. LANIER:

14 Q. "The role of large diameter bearings" by Thomas
15 Schmalzried.

16 Do you see this presentation?

17 A. I do.

18 Q. Using the same slide that's offensive, isn't he?

19 A. It's very offensive, I've said that.

20 Q. And yet again we've got another presentation that is
21 supported by DePuy and the Piedmont Foundation. Do you see
22 that?

23 A. I see where he's written that, but --

24 Q. In fact --

25 A. -- I don't believe we supported it.

1 Q. -- I don't know if his thank is to DePuy or to the
2 audience, do you?

3 Isn't it fair to say that when we try to assess whether
4 or not at least Dr. Thomas Schmalzried belongs on the side of
5 marketing and sales or on the side of science it sure seems
6 that he's a little bit more marketing and sales, fair?

7 A. I disagree.

8 Q. In fact, he had dealings with you personally because he
9 felt like he was being excluded from some sales meetings,
10 didn't he?

11 A. Not that I recall.

12 Q. You had a number of your doctors pursue you personally
13 because they felt like they weren't getting the attention they
14 needed, true?

15 A. I don't know the answer to that.

16 Q. All right. Next subject.

17 Mr. Sarver said in opening that there had been excellent
18 long-term results in Europe. And he put up a chart, a slide.

19 MR. LANIER: Could I -- could we look for that?

20 I think it was around 555.

21 THE COMPUTER OPERATOR: Say again.

22 MR. LANIER: Excellent long-term results in Europe.
23 It was a chart that had a number of different places.

24 BY MR. LANIER:

25 Q. You are familiar with the European market, aren't you?

1 A. I am, yes.

2 Q. You are familiar with the British Journal Registry,
3 aren't you?

4 A. The National Joint Registry?

5 Q. Yes.

6 A. Yes.

7 Q. There you go. Put it up. Put it up.

8 Long-term results with metal-on-metal in Europe.

9 Do you see that?

10 A. I see that, yes.

11 Q. Okay. Let's make a note of these real quick that
12 Mr. Sarver was showing the jury.

13 What we see here -- oh, we lost it.

14 Oh, all right. Go back to -- we're going to have to
15 memorize -- no, we're going to use --

16 MR. LANIER: May I use the chart, Your Honor, the
17 pull-out?

18 THE COURT: Yes.

19 MR. LANIER: Thank you.

20 BY MR. LANIER:

21 Q. Okay. This is so we can remember.

22 MR. LANIER: Thank you, Ronnie.

23 THE COURT: Do I need to call Vanna White and bring
24 her down here?

25 MR. LANIER: She would do a better job.

1 THE COURT: She sure would.

2 MR. LANIER: Make sure we got these numbers down,
3 because I got some questions for you.

4 BY MR. LANIER:

5 Q. Okay. This is not, by the way, DePuy Pinnacle
6 metal-on-metal in Europe. This is metal-on-metal in general;
7 is that what you understand?

8 A. Yeah. I didn't create the slide deck or the chart, of
9 course.

10 Q. All right. Well, let's just make sure we've got it.

11 A. Just going with the title.

12 Q. Lass is 93 percent at 18.8 years. Right?

13 A. Okay.

14 Q. And then we've got Randelli, which is 94 percent at 13
15 years.

16 Are you with me?

17 A. I'm following you.

18 Q. And we've got Nikolaou -- Nikolaou, which is 98.4 percent
19 at 11 years.

20 And last, but not least, Delaunay, which is 100 percent
21 at 10 years.

22 You got it?

23 A. Got it.

24 Q. Thank you.

25 A. Are all these single centers, do you know whether

1 they' re --

2 Q. They' re whatever Mr. Sarver picked for his opening
3 statement to the jury to try and tell the jury why he wins on
4 your behalf.

5 So what I'd like to do is show you --

6 MR. LANIER: Your Honor, we've marked the National
7 Joint Registry of the UK, the most up-to-date 2015 numbers, as
8 demonstrative 3193. May I approach the witness with a couple
9 of pages?

10 THE COURT: Yes.

11 MR. LANIER: Any -- I --

12 THE COURT: Do you have --

13 MR. QUATTLEBAUM: No objection.

14 THE COURT: No objection. Okay.

15 BY MR. LANIER:

16 Q. Sir, I have pulled out a couple of numbers that are
17 relevant, but this is the largest registry there is, largest
18 official registry. Greatest numbers, right?

19 A. I'm sorry, yes.

20 Q. Okay. Now, if you look, we're going to see -- I have to
21 do it a little bit close up.

22 It's got Corail -- actually it's pronounced Corail but it
23 looks like Corail to me, but I'm from Lubbock. How do you
24 pronounce it?

25 A. Corail.

1 Q. Corail. Are you sure it's not Corail?

2 A. It is in Texas.

3 Q. Okay. Well, maybe just in Lubbock. I wouldn't go much
4 beyond that. Muleshoe, maybe.

5 Corail/Pinnacle, so this is the Pinnacle system. And
6 it's got metal-on-metal. It's also got ceramic-on-plastic, or
7 poly, ceramic-on-ceramic, and ceramic-on-metal, and
8 metal-on-poly. Do you see that?

9 A. Yes, I'm following along.

10 Q. All right. And metal-on-poly is the one that's big in
11 the United States. Right?

12 And metal-on-metal.

13 A. I'm sorry. Yeah. Correct.

14 Q. Okay. Let's look at the metal-on-metal.

15 If we look at the metal-on-metal out at five years we've
16 got 5.15 percent. That's out five years. Do you see that?

17 That doesn't do us, we need 10 years.

18 If you look at it out 10 years, 15.69 percent from 10
19 years. You got that?

20 Do you see?

21 A. Yeah. Sorry. I'm just trying to follow along.

22 Q. That's okay.

23 By the way, metal-on-poly is working great, isn't it?

24 Do you see that metal-on-poly number?

25 A. Can you circle it?

1 Q. This is how many are revised, aren't they?

2 This is the probability of revision.

3 Do you follow what I mean?

4 A. I see that.

5 Q. Okay. All I'm getting at, sir, is if we want to put the
6 statistic for DePuy's metal-on-metal from the nonbiased
7 government, you've got 100 minus 15.69. And that's going to
8 equal 84 percent, 84.3 percent. Right?

9 A. Yes. And you have to understand the background -- before
10 you can compare like you're going to do here, you've got to
11 understand the background of the statistics that Mr. Sarver
12 used and you've got to understand the statistics here. And
13 you've got to understand -- get underneath it all and
14 understand what is creating this revision rate, both with the
15 studies that Mr. Sarver talked about as well as the studies in
16 this particular study, the registry.

17 So to compare them, Mr. Lanier, like you're doing, I'm
18 not sure it's a reasonable treatment of the statistics.

19 MR. LANIER: Objection, nonresponsive.

20 THE COURT: Sustained.

21 BY MR. LANIER:

22 Q. What question were you answering?

23 A. I was interpreting your question.

24 Q. What question -- what did you think I asked?

25 A. I thought we were having a dialogue around these numbers.

1 Q. No, I asked you if 100 minus 15.69 equals 84.31 percent.
2 Does it?

3 A. You've done the math correctly.

4 Q. Now, Mr. Sarver -- let's get into the speech you gave
5 now.

6 Okay. Mr. Sarver put up for the jury these numbers and
7 said that metal-on-metal has been doing wonderfully well in
8 Europe. And he's cherry-picked certain numbers from certain
9 studies and put up here. Do you see that?

10 A. I don't know how he chose those. He's behind you,
11 perhaps you could ask him.

12 Q. Well, he won't take the stand. I've got to ask you, sir.
13 Do -- you're the man who was over this for quite a period of
14 time.

15 The bottom line is if Mr. Sarver's numbers accurately
16 reflect the performance of metal-on-metal in Europe, then
17 y'all are horrible, aren't you?

18 A. I disagree, because --

19 THE COURT: Stop.

20 Okay. We're going to quit for the day, ladies and
21 gentlemen.

22 Oh, wait, let me -- let me let you finish. Go ahead. I
23 didn't mean to cut you off, Mr. Ekdahl.

24 THE WITNESS: I'm fine, sir. I'll leave it there.

25 THE COURT: You can finish if you want to.

1 THE WITNESS: I'm sure we'll be back at this
2 tomorrow.

3 THE COURT: I'm sure we will.

4 (Laughter)

5 That's the most prophetic statement said today.

6 Y'all this is your first day of a full day of listening
7 and sitting, and it's different. It's just different. I know
8 all of y'all have jobs where you do some sitting, that kind of
9 thing, but it's very different listening to me, listening to
10 the lawyers, trying to stay concentrated.

11 So tonight there are two big events. Biggest one,
12 according to my wife, is the Bachelor is on tonight, so I
13 don't get to watch on the big TV, and the other, of course, is
14 the football playoff between Alabama and Clemson.

15 All I'm asking is make sure -- whatever your normal sleep
16 patterns, get plenty of sleep tonight because it's your first
17 time to do it. I guarantee you, I don't know any one of
18 y'all, you're tired. This is a whooping. It just is. But
19 it's an important process. I promise you, your body will
20 adjust, you'll get used to it.

21 You've been very -- I watched you today, whether you knew
22 I was or not. Y'all have been very alert. It's important you
23 do that. And I just want to thank you for working so hard
24 today.

25 Tomorrow it will be cooler in here. Bring your warm

1 things again. I know it got hot, but I'll work on it, just
2 like I worked on when the lights flew off or whatever happened
3 earlier.

4 We will hope the building doesn't fall down tonight.
5 It's a government building. But short of that happening,
6 we'll be right back here tomorrow at 9:00 o'clock. You'll see
7 Mr. Everett right over there. We'll see you back then.

8 Don't talk about the case tonight. Don't do any research
9 on it on your own. We'll see you back in the morning. Leave
10 your notes in the jury room.

11 Thank you.

12 (End of proceedings.)

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C E R T I F I C A T I O N

I, PAMELA J. WILSON, CSR, certify that the foregoing is a transcript from the record of the proceedings in the foregoing entitled matter.

I further certify that the transcript fees format comply with those prescribed by the Court and the Judicial Conference of the United States.

This the 11th day of January, 2016.

s/Pamela J. Wilson
PAMELA J. WILSON, CRR, RMR
Official Court Reporter
The Northern District of Texas
Dallas Division